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Aldicarb

Interim Registration Review Decision
Case Number 0140

December 2017

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Date: 12/22/17

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I. INTRODUCTION

This document is the Environmental Protection Agency's (EPA or the Agency) *Interim Registration Review Decision for Aldicarb* (Case# 0140, PC Code 098301), and is being issued pursuant to 40 CFR sections 155.56 and 155.58. A registration review decision is the Agency's determination that a pesticide meets, or does not meet, the standard for registration in the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The Agency may issue, when it determines it to be appropriate, an Interim Registration Review Decision before completing a registration review. Among other things, the Interim Registration Review Decision may: 1) require new risk mitigation measures; 2) impose interim risk mitigation measures; 3) identify additional data or other information required to complete the review; and 4) include schedules for submitting the required data, conducting the new risk assessment, and completing the registration review. For further information on aldicarb, additional documents can be found in EPA's public docket (EPA-HQ-OPP-2012-0161) at www.regulations.gov.

FIFRA, as amended by the Food Quality Protection Act (FQPA) of 1996, mandated the continuous review of existing pesticides. All pesticides distributed or sold in the United States (U.S.) generally must be registered by the EPA based on scientific data showing that they will not cause unreasonable risks to human health or to the environment when used as directed on product labeling. The registration review program is intended to make sure that, as the ability to assess and reduce risk evolves and as policies and practices change, all registered pesticides continue to meet the statutory standard of no unreasonable adverse effects. Changes in science, public policy, and pesticide use practices will occur over time. Through the registration review program, the Agency periodically re-evaluates pesticides to make sure that as these changes occur, products in the marketplace can continue to be used safely. Information on this program is provided at http://www2.epa.gov/pesticide-reevaluation. In 2006, the Agency implemented the registration review program pursuant to FIFRA section 3(g) and will review each registered pesticide every 15 years to determine whether it continues to meet the FIFRA standard for registration.

EPA is issuing an interim registration review decision for aldicarb so that it can move forward with aspects of the registration review that are complete and implement interim risk mitigation. The Agency is currently working with the U.S. Fish and Wildlife Service and the National Marine Fisheries Service (together, the Services) to develop methodologies for conducting national endangered (listed) species assessments for pesticides. Therefore, although EPA has not yet fully evaluated risks to listed species, the Agency will complete its endangered species assessment and any necessary consultation with the Services for aldicarb prior to completing the aldicarb registration review. Likewise, the Agency will complete endocrine screening for aldicarb, pursuant to the Federal Food, Drug, and Cosmetic Act (FFDCA) §408(p) before completing this registration review. Lastly, EPA will determine whether additional pollinator exposure and effects data are necessary to make a final registration review decision for aldicarb and, if so, issue a data call-in (DCI) to obtain any such data prior to completing the aldicarb registration review.

Summary of Aldicarb Registration Review

Aldicarb is an N-methyl carbamate insecticide that is marketed only as a granular product with a concentration of 15 percent active ingredient. Aldicarb products are registered for use to control certain insects, mites, and nematodes. There are no residential uses of aldicarb. Aldicarb products are used in agricultural areas and are registered for use on cotton, dry beans, peanuts, soybeans, sugar beets, and sweet potatoes.

This document is organized in five sections: the *Introduction*, which includes this summary and a summary of public comments and EPA's responses; *Use and Usage*, which describes how and why aldicarb is used and summarizes data on its use; *Scientific Assessments*, which summarizes EPA's risk assessments, any revisions to the previous risk assessments, and risk conclusions; the *Interim Registration Review Decision*, which describes the mitigation measures required to address risks of concern and the regulatory rationale for EPA's interim registration review decision; and, last, the *Next Steps and Timeline* for completion of this registration review.

Pursuant to 40 CFR section 155.50, EPA formally initiated registration review for aldicarb (Case #0140). Table 1 below highlights significant events that have occurred during the registration review of aldicarb:

Table 1. Significant events during the Registration Review of aldicarb.

Date	Action
July 6, 2012	Aldicarb Preliminary Work Plan (PWP), scoping document, and problem formulation were posted to the docket for a 60-day public comment period.
December 21, 2012	Final Work Plan (FWP) for aldicarb was completed. Six public comments concerning the PWP were submitted by the registrant, sugar beet industry representatives, a non-profit and an independent scientific research advocate. The comments resulted in a change to the anticipated data requirements in the DCI and the projected registration review timeline, but not the planned assessments. See the FWP for a comprehensive summary of the comments and the agency's responses, available in regulations.gov at EPA-HQ-OPP-2012-0161-0017.
April 16, 2013	Generic Data Call-In (GDCI) for aldicarb was issued including studies identified in the FWP. All data requested in the DCI have been received or waived. Additional information is needed to fulfill the soil ECM/ILV data requirement.
April 26, 2016	The Agency announced the availability of the *Preliminary Ecological Risk Assessment for the Registration Review of Aldicarb* and the *Aldicarb: Draft Human Health Risk Assessment in Support of Registration Review* for a 60-day public comment period. Fifty-six comments were received from the registrant, agriculture industry representatives, extension agents, the National Potato Council, various cotton industry groups, university representatives, the United States Department of Agriculture (USDA), the Center for Biological Diversity, Earthjustice, and the general public. Many of the comments focused on the benefits of aldicarb. Comments from the registrant proposed mitigation measures to address the risks identified in the Draft Human Health and Draft Ecological and Environmental Fate Risk Assessments. The mitigation proposed in the comments affected the risk assessment conclusions. Comments are addressed in Appendix A of the PID and the following documents: *Response to Public Comments Received on the Draft Aldicarb Human Health Risk Assessment* (dated November 3, 2016) and *Response to Comments Regarding the Preliminary Ecological Risk Assessment for the Registration Review of Aldicarb* (dated December 21, 2016). These response documents were published in the registration review docket for aldicarb (EPA-HQ-OPP-2012-0161-0092 and EPA-HQ-OPP-2012-0161-0095).
May 25, 2017	The Agency published the Pesticide Re-Evaluation Division (PRD) document *Aldicarb Proposed Interim Registration Review Decision* (dated December 22, 2016) as well as

Table 1. Significant events during the Registration Review of aldicarb.	
Date	**Action**
	Biological and Economic Division's (BEAD's) documents entitled the *Proportion of Imported Oranges, Orange Juice, Potatoes, and Sweet Potatoes as a Component of Total Consumption in the United States and Review of Registrant submitted Percent Crop Treated Estimate for Sweet Potatoes: Data to Support the Human Dietary Risk Assessment of Aldicarb* (dated October 28, 2016) and *Alternatives Assessment for Aldicarb on Cotton, Dry Beans, Peanuts, Soybeans, Sugar Beets, and Sweet Potatoes* (dated December 21, 2016) in the registration review docket for a 60-day public comment period. Four comments were received on the proposed interim decision, which are discussed in Appendix A of this document and the following documents: *Aldicarb: Response to Comments from AgLogic Chemical, LLC on the Proposed Interim Decision (PID) for the Registration Review of Aldicarb* (dated November 30, 2017), *Response to Public Comments Received on the Aldicarb Proposed Interim Registration Review Decision* (dated December 5, 2017), *Revised Proportion of Imported Oranges, Orange Juice, Potatoes, and Sweet Potatoes as a Component of Total Consumption in the United States and Review of the Registrant Submitted Percent Crop Treated Estimate for Sweet Potatoes: Data to Support the Human Dietary Risk Assessment of Aldicarb* (dated March 1, 2017), and *BEAD Characterization of Sugar Beet Planting Practices in Support of the Human Health Risk Assessment for Aldicarb* (dated November 1, 2017). The comments from AgLogic, the registrant, changed elements of the Agency's interim decision for aldicarb.
December 2017	The Agency is now completing the Interim Decision for Aldicarb.

II. USE AND USAGE

Aldicarb is a systemic carbamate insecticide, acaricide, and nematicide used on cotton, dry beans, peanuts, soybeans, sugar beets, and sweet potatoes. Aldicarb is formulated as a granular pesticide and is usually applied early in the growing season (pre-plant, at-plant, or early post-emergent) using ground application equipment. Aldicarb may be applied as a soil treatment by any of the following methods: sidedress, band/T-band, and in-furrow treatment. When applied as a post-emergence application to peanuts (pegging application), aldicarb may be applied in a band 12 to 18 inches wide onto the row and into the plant canopy. The granules must be dislodged from the plant and the application should be followed immediately by irrigation (unless rainfall is received). Aldicarb is a Restricted Use Pesticide (RUP) and may be purchased and used only by certified applicators or persons under their direct supervision.

Based on private market pesticide usage data from 1998-2010, the usage of aldicarb (excluding sweet potatoes because usage data are not available) was relatively stable. During the years 2006-2010, approximately 3.7 million pounds of aldicarb was used to treat 3.6 million acres. In August 2010, the Agency signed a Memorandum of Agreement (MOA) with Bayer CropScience (Bayer) to phase-out the use of aldicarb. Bayer was the only registrant at the time. Existing stocks of Bayer's aldicarb products were available for growers until December 31, 2016. Usage data from 2010-2014 indicate that usage of aldicarb had largely ceased by 2013.

A new aldicarb registrant, AgLogic Chemical LLC (AgLogic), registered an aldicarb end use product for use on cotton, dry beans, peanuts, soybeans, sugar beets, and sweet potatoes in 2011 (corn cob based) and another end use product in 2016 (gypsum-based). AgLogic did not begin manufacturing aldicarb until 2016, and only in limited quantities. Usage information is not yet available for these products. See *BEAD Chemical Profile for Registration Review: Aldicarb* (dated December 8, 2011), *BEAD Review of Aldicarb (098301) Use Summary Tables Submitted*

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by AgLogic (dated August 27, 2015), *Proportion of Imported Oranges, Orange Juice, Potatoes, and Sweet Potatoes as a Component of Total Consumption in the United States and Review of Registrant submitted Percent Crop Treated Estimate for Sweet Potatoes: Data to Support the Human Dietary Risk Assessment of Aldicarb* (dated October 28, 2016), and *Alternatives Assessment for Aldicarb on Cotton, Dry Beans, Peanuts, Soybeans, Sugar Beets, and Sweet Potatoes* (dated December 21, 2016) for additional details on aldicarb use and usage.

III. SCIENTIFIC ASSESSMENTS

A. Human Health Risk

The most current Agency science policies and risk assessment methodologies were used to prepare a quantitative human health risk assessment in support of the registration review of aldicarb, a summary of which is presented below. For a detailed discussion of the human health assessment for aldicarb, see the *Aldicarb: Draft Human Health Risk Assessment for Registration Review* (dated March 25, 2016), *Response to Public Comments Received on the Draft Aldicarb Human Health Risk Assessment* (dated November 3, 2016), *Aldicarb Revised Acute Aggregate Dietary (Food and Drinking Water) Exposure and Risk Assessments for Registration Review Risk Assessment* (dated November 28, 2017), and *Response to Public Comments Received on the Aldicarb Proposed Interim Registration Review Decision* (dated December 5, 2017). These documents are available in the public docket.

1. Risk Conclusions

Dietary (Food Risks)

Aldicarb is an N-methyl carbamate (NMC). NMCs have a unique mode of action that results in rapid onset and recovery of the acetylcholinesterase (AChE) enzyme (Insecticide Resistance Action Committee Group 1A). The time to peak inhibition for NMCs is typically between 15 to 45 minutes while complete recovery of the enzyme is achieved within minutes to hours (EPA 2007 Revised NMC Cumulative Risk Assessment). Therefore, for NMCs, repeated daily exposure does not result in an increased inhibition of AChE since enzyme recovery is complete before the next acute exposure, and only acute exposure durations are assessed for NMCs, including aldicarb. A chronic dietary assessment was not conducted since recovery data demonstrate that the rapid recovery of cholinesterase following acute exposure to aldicarb prevents cumulative toxicity; consequently, longer-term exposures are considered a series of acute exposures.

A highly refined acute dietary (food only) exposure assessment was conducted using the Dietary Exposure Evaluation Model (DEEM-FCID™, Version 2.03) for all existing food uses of aldicarb in March 2016 (EPA, 2016a). Estimated acute dietary exposure and risk estimates were below EPA's level of concern (LOC) for the U.S. population and all population subgroups. Exposure was equivalent to 25% of the acute population adjusted dose (aPAD) at the 99.9th percentile of exposure for the general U.S. population and 65% of the aPAD for the highest exposed population subgroup, children 1-2 years old.

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To further characterize the exposures to aldicarb residues in registered commodities and commodities with import tolerances, the Agency conducted a commodity specific analysis (CSA) in March 2016. The consumption values in DEEM-FCID™ consider a wide variety of exposures, from commodities blended in soup or baked goods, to represent foods "as consumed" (e.g., apple pie). The CSA considers the potential acute exposure and risk following a single consumption event of a specific commodity, were that commodity to contain aldicarb residues equal to the highest concentration measured over years of measurements in PDP monitoring. The 2016 CSA resulted in exposure estimates above the LOC for children following the consumption of an estimated single serving of sweet potato (domestic and import) or potato (import). These estimates represent exposures beyond the 99.9th percentile considered as the point of regulation for the Agency's distributional human health dietary risk assessments in cases where percent crop treated data are used. A similar analysis performed for other crops to which aldicarb can be applied did not result in estimated exposures that would exceed an LOC.

During the public comment period for the PID, information was received from the governments of Costa Rica and Mexico regarding the use of aldicarb in those countries. The Agency revised the percent crop treated estimates with that information (EPA, 2017a) and incorporated the new estimates in a revised dietary exposure assessment in November 2017 (EPA, 2017b). In the revised assessment, estimated acute dietary (food only) exposure and risk estimates were still not of concern for the U.S. population and all population subgroups. Food only risk was equivalent to 27% of the acute population adjusted dose (aPAD) at the 99.9th percentile of exposure for the general U.S. population and 74% of the aPAD for the highest exposed population subgroup, children 1-2 years old.

In the 2017 revised dietary assessment, the CSA analysis for potato was removed because new information indicates that aldicarb-treated fresh potatoes are not imported to the United States and there is no domestic aldicarb use on potato (EPA, 2017b). The CSA analysis for sweet potato was retained, and is described below.

Dietary (Water Risks)

Acute dietary exposure estimates (based on initial drinking water exposure estimates only) in the Draft Risk Assessment (DRA) were above EPA's LOC at the 99.9th percentile of exposure. Dietary exposure estimates for drinking water alone ranged from 1,400% to 2,900%, and 150% to 340% of the aPAD at the 99.9th percentile of exposure for the general population and most population subgroups using the scenarios that resulted in the highest estimated drinking water concentration (EDWC) (MN sugar beets) and the lowest EDWC (CA cotton), respectively. The acute dietary exposure estimates were based on estimated surface water concentrations simulated with the Surface Water Concentration Calculator (SWCC).

The DRA also estimated a potential for significant drinking water exposure from groundwater sources under certain environmental conditions. The EDWC for chronic exposure was derived from these estimates. The Pesticide Root Zone Model for Groundwater (PRZM-GW) uses six very vulnerable scenarios as screening surrogates for the entire country. These scenarios are distinguished by their sandy soils and very shallow water tables, which range from 10 to 30 feet below the surface.

Current aldicarb labels include mitigation measures which were previously added to reduce potential exposure in drinking water derived from vulnerable sources similar to those simulated by PRZM-GW. For instance, aldicarb labels are proscriptive in listing states in which the chemical can be applied, and use is not allowed in three of the states represented by PRZM-GW scenarios (Wisconsin, Delaware and Maryland). Other PRZM-GW scenarios represent states in which users must observe setbacks from drinking water wells of up to 1,100 feet in areas where the soils are sandy and water tables are shallow. The six scenarios in PRZM-GW are meant to be surrogates for vulnerable soils around the country, and the aldicarb label allows setbacks of 50 feet in some states in which aldicarb can be used.

The highest EDWCs from PRZM-GW were derived from the Florida Central Ridge scenario, which simulates leaching through a sandy soil profile to a 10-foot deep well screen at the top of the water table. Although aldicarb labels require a minimum of a 300-foot drinking water well setback in Florida, the EDWCs reflect a 50-foot setback. The highest concentrations calculated with the Florida Central Ridge scenario were for acidic soil and water conditions. Output from the PRZM-GW model is sensitive to the hydrolysis rate of the chemical, and the hydrolysis of aldicarb is pH-dependent. Aldicarb hydrolyzes most slowly under acidic conditions, and more quickly under more alkaline conditions. This is reflected in the concentrations simulated below in Table 2, which do not include the 50-foot well setback:

Table 2. PRZM-GW model outputs for the Florida central ridge scenario.

Modeled Scenario	Groundwater pH	Max. Daily Conc. (µg/L)	Mean Breakthrough Time (yrs)	Post-breakthrough Mean (µg/L)
FL Central Ridge	6	100	3.4	31
	7	33		3.5
	8	1.25		0.002

In the revised dietary assessment, the Agency considered the contribution of aldicarb residues in drinking water through a drinking water level of comparison (DWLOC) approach. Thus, a DWLOC level is determined by including water concentrations with food residues sufficient to give a risk level of approximately 100% aPAD for the most highly exposed population subgroup. A DWLOC value of 0.87 ppb was determined. Any aldicarb use patterns that result in estimated drinking water concentrations (EDWCs) lower than 0.87 ppb will not be of concern. Conversely, any aldicarb use patterns that result in EDWCs equal to or higher than 0.87 ppb will be of concern. See Section IV.A.1 in this document for a discussion of the DWLOC and EDWCs.

Non-Occupational Risks

There are no registered residential uses of aldicarb; therefore, a quantitative residential handler and post-application assessment was not conducted. The aldicarb end use products are granular formulations and are not anticipated to result in spray drift because of how it is applied (pre-plant/post-emergent soil incorporation).

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Aggregate Exposure/Risk Characterization

In accordance with the FQPA, EPA must consider and aggregate (add) pesticide exposures and risks from three major sources: food, drinking water, and residential exposures. In an aggregate assessment, exposures from relevant sources are added together and compared to quantitative estimates of hazard (e.g., a no observed adverse effect level (NOAEL) or PAD), or the risks themselves can be aggregated. When aggregating exposures and risks from various sources, EPA considers both the route and duration of exposure.

There are no residential uses of aldicarb. Therefore, aggregate risks only include acute dietary contributions. The acute dietary risk estimates for drinking water only and food plus drinking water were of concern in the DRA (2,900% of the aPAD for all infants <1-year old, the highest exposed population subgroup). However, the revised dietary assessment has calculated a DWLOC of 0.87 ppb and concluded that there are no risk concerns for aldicarb use patterns that result in EDWCs lower than the DWLOC of 0.87 ppb.

Cumulative Exposure/Risk Characterization

The FQPA requires the Agency to consider the cumulative risks of chemicals sharing a common mechanism of toxicity. Aldicarb is a member of the NMC common mechanism group. NMCs like aldicarb share the ability to inhibit AChE through phosphorylation of the serine residue on the enzyme leading to accumulation of acetylcholine and ultimately cholinergic neurotoxicity. This shared mode of action/adverse outcome pathway is the basis for the NMC common mechanism grouping per the Office of Pesticide Program's (OPP's) *Guidance for Identifying Pesticide Chemicals and Other Substances that have a Common Mechanism of Toxicity*. The 2007 Cumulative Risk Assessment and the subsequent revision used brain AChE inhibition in female rats as the source of dose response data for the relative potency factors and points of departure for each NMC, including aldicarb. Prior to the completion of registration review, EPA will update the NMC cumulative risk assessment to incorporate new toxicity and exposure information available since 2007.

Short- and Intermediate- Term Handler Risk

EPA uses the term "handlers" to describe those individuals who are involved in the pesticide application process. EPA has determined that there are potential exposures to handlers during application of aldicarb. Scenarios assessed were (1) open mixing/loading and open cab application using label-specified PPE, and (2) closed mixing/loading and closed-cab application (i.e., engineering controls).

The current label-required Personal Protective Equipment (PPE) varies depending on the handling scenario. For open pour handling, the PPE is coveralls over a long-sleeved shirt and long pants, chemical-resistant gloves made of any waterproof material, and chemical-resistant footwear plus socks. In addition, during loading, equipment cleaning or repair, or spill clean-up, the labeling requires handlers to wear protective eyewear (goggles or face shield), a chemical-resistant apron, and a National Institute for Occupational Safety and Health (NIOSH)-approved respirator with a dust/mist filter. The exception to the above PPE requirements are when

engineering controls (i.e., a closed loading/application system) are used. The restricted entry interval (REI) on the current labeling is 48 hours.

The occupational assessments were completed based on an available chemical-specific occupational exposure monitoring study[1] (used to assess the use of PPE during open pour/open cab applications) and based on surrogate data (i.e., the Pesticide Handlers Exposure Database (PHED); used to assess the use of engineering controls during applications). Occupational handlers are assessed assuming short- and intermediate-term dermal and inhalation exposure.

The DRA found only two occupational handler risk estimates of concern for the registered uses of aldicarb on agricultural crops with label-required PPE (i.e., a double layer of clothing and a standard filtering face-piece respirator). EPA identified potential risks of concern when the LOC for the occupational risk estimates results in a margin of exposure (MOE) of less than 10, which includes a 10X intra-species uncertainty factor and a 1X inter-species uncertainty factor (reduced from 10X because the endpoint is derived from a human study). For the open pour/open cab application scenarios, using chemical-specific unit exposure data and assuming use of label required PPE, there were combined dermal and inhalation risk estimates of concern (i.e., MOEs are < 10) for two scenarios. This risk was driven by the dermal component. Mixer/loader risk estimates were of concern for the use on sugar beets at the maximum rate of 4.95 lb ai/A (MOE = 4.5) for nematode control and the maximum rate of 3 lb ai/A (MOE = 7.4) for control of other pests listed on the label. See Table 3.

During the public comment period for the proposed interim decision, AgLogic commented that the Agency should consider the actual acres of sugar beets treated with aldicarb in a given day, and the documented half-life of aldicarb cholinesterase inhibition in the human body as a result of the reversibility of effects. AgLogic did not agree with the Agency's assumption of 200 acres treated in a day and provided assumptions for aldicarb applications to sugar beets for the Agency to consider. The Agency reviewed the information provided and also analyzed sugar beet practices. The Agency determined that 50 to 105 acres of sugar beets could be planted per 8-hour workday depending on the application equipment used (EPA, 2017c). Incorporating the more conservative value of 105 acres into the occupational assessment yields the following revised mixer/loader risk estimates for the use of aldicarb on sugar beets as summarized in Table 3. At the maximum rate of 4.95 lb ai/A (used for nematode control), the MOE is 8.5 and at the rate of 3 lb ai/A (used for control of other pests listed on the label), the MOE is 14.

Table 3. Occupational handler non-cancer exposure and risk estimates of concern for aldicarb.

Crop	Rate (lb ai/A)	Area Treated (acres)	Dermal MOE (LOC = 10)	Inhalation MOE (LOC = 10)	Combined MOE (LOC = 10)
Sugar Beet	4.95	200	4.8	75	4.5
		105	9.1	140	8.5
	3	200	7.9	120	7.4
		105	15	240	14

Open Pour/Open Cab Application Using Label-Required PPE (Double layer of clothing and PF5 Respirator) Using Chemical-Specific Data.

[1] Worker Loader and Applicator Exposure to Temik 15G (10/12/95) Sponsor: Rhone Poulenc Ag Company, 2 TW Alexander Drive, Research Triangle Park NC 27709 (EPA MRID 438525-01)

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While it is possible for a mixer/loader to be exposed to the entire amount handled once per day, the Agency acknowledges that it is likely that the full amount of product is not loaded in one event per day. Therefore, multiple mixing/loading events could be considered and inclusion of the aldicarb cholinesterase inhibition half-life into the occupational assessment could be a reasonable refinement. Using the revised acreage listed above (i.e., 105 acres) split into two events separated by 2 hours, and including the aldicarb cholinesterase inhibition half-life, the MOE for mixing/loading granules for sugar beets at the maximum application rate of 4.95 lb ai/A is 11 with a LOC of 10. When considering these risk estimates, the following points are also acknowledged by the Agency:

- A default 100% dermal absorption factor was used to estimate the dermal dose. Given that aldicarb is handled only as a granular, it is unlikely that 100% absorption would occur; however, the exact absorption factor could not be determined from the available toxicological studies.
- The 105-acre/day estimate is considered high-end for at-plant tractor granule herbicide applications.
- Information regarding the flux rate of aldicarb through the skin is not available, therefore, the calculation assumes immediate absorption through the skin.

Even though PHED data were presented in the preliminary risk assessment, the Agency believes that the chemical-specific data is more appropriate in this instance and those are the only data presented in this document.

Post-Application Occupational Risk

EPA uses the term "post-application" to describe exposures that occur when individuals are present in an environment that has been previously treated with a pesticide (also referred to as reentry exposure). Such exposures may occur when workers enter previously treated areas to perform job functions, including activities related to crop production, such as scouting for pests. Post-application exposure levels vary over time and depend on such things as the type of activity, the nature of the crop or target that was treated, the type of pesticide application, and the chemical's degradation properties. In addition, the timing of pesticide applications, relative to harvest activities, can greatly reduce the potential for post-application exposure.

A quantitative post-application assessment has not been conducted for aldicarb because aldicarb is soil incorporated and there is limited potential for worker dermal exposure to soil incorporated pesticides.

The REI specified on the existing labels (48 hours) is based on the acute toxicity of aldicarb. Aldicarb is classified as Toxicity Category I via the dermal, oral, and inhalation routes of exposure. Due to severe effects (death) following corneal and dermal dosing, dermal and eye irritation studies were waived in the acute toxicity database. Because of the limited worker exposure profile (soil-incorporation), the REI on the labels is adequate to protect for worker exposure. Therefore, the 40 CFR 156 subpart K Worker Protection Statement interim REI of 48 hours is adequate to protect agricultural workers from post-application exposures to aldicarb.

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2. Human Incidents

Since the 2016 proposed interim decision was published, the Agency has reviewed the incident databases and updated the reported incident data here. The Agency completed a review of aldicarb incidents in the OPP Incident Data Systems (IDS), for the period covering January 2006 to December 2017, and the Centers for Disease Control and Prevention/NIOSH Sentinel Event Notification System for Occupational Risk-Pesticides (SENSOR) database for the period covering 1998-2014. In the Main IDS, there are 19 cases reported for aldicarb—one fatality, one high severity, two major severity, 14 moderate severity, one minor severity. The doctor who conducted the autopsy in the 2006 fatality case did not consider the cause of death to be related to the reported aldicarb exposure. In the Aggregate IDS, there are 13 cases reported. Because these cases are reported as counts, which include minor, unknown or no effects, there is no unique report that provides details about the incidents and single chemical incidents are not distinguished from multiple chemical incidents. The SENSOR database identified 87 cases—one case was fatal (an intentional exposure in 2005), 6 cases were classified as high in severity, 36 cases were moderate in severity, 44 cases were low in severity. In total, 18 of the reported cases in the SENSOR database were intentional exposures. Based on the low frequency and generally low severity of incident cases reported for aldicarb, there does not appear to be a concern at this time that would warrant further investigation. The Agency will continue to monitor the incident information and, if a concern is triggered, additional analysis will be conducted. For additional detail, see *Aldicarb: Tier I Update of Human Incidents for Draft Risk Assessment* available in the public docket EPA-HQ-OPP-2012-0161-0024.

3. Tolerances

Tolerances are established in the 40 CFR § 180.269 for the use of aldicarb on bean, sugar beet, coffee, cotton, grapefruit, lemon, lime, orange, peanut, pecan, potato, soybean, sugarcane and sweet potato. These tolerances are based on measurement of combined residues of aldicarb and its cholinesterase-inhibiting metabolites aldicarb sulfoxide [2-methyl-2-(methylsulfinyl) propionaldehyde O-(methyl carbamoyl) oxime] and aldicarb sulfone [2-methyl-2-(methylsulfonyl) propionaldehyde O-(methyl carbamoyl) oxime] and range from 0.02 to 1 ppm. The tolerances for dry bean, sugar beet, cotton, peanut, soybean and sweet potato are based on domestic uses of aldicarb. Coffee was included in the 2010 dietary assessment in support of use on the imported commodity. Although tolerances for potato, citrus, coffee, pecan, and sugarcane are established in the Code of Federal Regulations (CFR), there are no registered uses for them in the U.S. As tolerances for these commodities are in the CFR at this time, these commodities were considered in the dietary assessment assuming that residues of aldicarb may be present in imported commodities. Sorghum tolerances also were considered in the dietary assessment for imported commodities, however, the sorghum tolerances were revoked in June 2016 after the preparation of the dietary assessment. Although livestock feedstuffs are associated with uses of aldicarb, tolerances are not established for livestock commodities because transfer of residues to livestock commodities is not expected (i.e., a 40 CFR §180.6(a)(3) situation applies). For additional detail, see *Aldicarb: Acute Aggregate Dietary (Food and Drinking Water) Exposure and Risk Assessments for Registration Review Risk Assessment* available in the public docket EPA-HQ-OPP-2012-0161-0032.

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4. Human Health Data Needs

870.7600 Dermal Penetration

In the proposed interim decision, EPA indicated that it intended to issue a DCI to obtain chemical-specific dermal absorption data. Dermal toxicity studies have been submitted to the Agency in the past, but none have been acceptable. Given the previous unsuccessful attempts to fulfill this data gap, the Agency analyzed additional information provided by the registrant to refine the occupational exposure assessment. Based on this additional analysis, the Agency has determined that the occupational risks identified for aldicarb applications to sugar beets are unlikely given the conservative assumptions used in the assessment. The Agency has concluded that dermal absorption data are not required at this time to make a registration review decision. However, the Agency may require this data for future risk assessments.

860.1650 Submittal of Analytical Reference Standards

Analytical standards for aldicarb (CAS# 116-06-3) and its metabolites aldicarb sulfoxide (CAS# 1646-87-3) and aldicarb sulfone (CAS# 1646-88-4) currently are not available at the EPA National Pesticide Standards Repository. Fresh samples of these standards must be submitted as soon as possible. They should be sent to the Analytical Chemistry Lab, which is located at Fort Meade, to the attention of either Theresa Cole or Thuy Nguyen at the following address:

USEPA
National Pesticide Standards Repository/Analytical Chemistry Branch/OPP
701 Mapes Road
Fort George G. Meade, MD 20755-5350

(Note that the mail will be returned if the extended zip code is not used.)

B. Ecological Risk

A summary of the Agency's ecological risk assessment is presented below. For a detailed discussion of the ecological risk assessment for aldicarb, see the *Preliminary Ecological Risk Assessment for the Registration Review of Aldicarb,* dated October 6, 2015 in the aldicarb registration review docket EPA-HQ-OPP-2012-0161-0021, which can be accessed at www.regulations.gov.

EPA is currently working with its federal partners and other stakeholders to implement an interim approach for assessing potential risk to listed species and their designated critical habitats. Once the scientific methods necessary to complete risk assessments for listed species and their designated critical habitats are finalized, the Agency will complete its endangered species assessment for aldicarb. As such, the risk conclusions described below pertain to non-listed species.

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1. Risk Conclusions

Aquatic Animals

Parent aldicarb and its degradates are highly mobile and are known to move to groundwater in sandy acidic soils. In poorly permeable soils, it will move with runoff. Following a rain event, aldicarb may reach aquatic environments as sheet and channel flow from areas of application, since aldicarb is moderately persistent in terrestrial environments and soluble in water. It is unlikely, though, that undissolved granules will reach surface water bodies as the granules themselves are not particularly mobile and in most cases buried below the surface. However, under the current label scenarios modeled for estimated exposure concentrations (EECs), all aquatic organisms, except aquatic plants, acute and chronic risk quotients (RQs) exceeded the non-listed LOCs of 0.5 and 1.0, respectively, for all current uses, see Tables 4-9. EECs for aquatic animals and plants in surface waters for labeled aldicarb applications are estimated using the Surface Water Concentration Calculator interface (SWCC version 1.21, dated February 19, 2015).

RQs resulting from EECs from currently supported (2015) uses:

Table 4. Aquatic exposure estimates for fish from aldicarb use sites (aldicarb only)[A].

Use Site	SWCC Scenario	1-in-10-year Peak (µg/L)	1-in-10-year 21-day Mean (µg/L)	1-in-10-year 60-day Mean (µg/L)
Cotton	MS cotton	28.9	25.7	19.9
Dry Beans	MI beans	28.2	26.4	21.8
Peanuts	NC peanuts	17.4	14.7	11.8
Soybeans	MS soybeans	22.3	19	13.2
Sugar Beets	MN sugar beets	**53**	**47.7**	**36.8**

[A] Maximum values are in bold.

Table 5. Aquatic exposure estimates for aquatic invertebrates from aldicarb use sites (aldicarb TTR)[A].

Use Site	SWCC Scenario	1-in-10-year Peak (µg/L)	1-in-10-year 21-day Mean (µg/L)	1-in-10-year 60-day Mean (µg/L)
Cotton	MS cotton	35.1	28.3	17.7
Dry Beans	MI beans	30.6	26.4	18.2
Peanuts	NC peanuts	21.1	15.6	10
Soybeans	MS soybeans	26.7	20.1	11.3
Sugar Beets	MN sugar beets	**78**	**59.7**	**38**

[A] Maximum values are in bold.

Table 6. Acute and chronic RQs for freshwater fish using maximum application rates with 99% incorporation efficiency (aldicarb only).

Crop Use	LC50 (ppb)	NOAEC (ppb)	EEC Initial/Peak (ppb)	EEC 60-day average (ppb)	Acute RQ (EEC/LC50)	Chronic RQ (EEC/ENEC)
Cotton	52	0.46	28.9	19.9	**0.55**	**43.26**
Dry Beans	52	0.46	28.2	21.8	**0.54**	**47.40**
Peanuts	52	0.46	17.4	11.8	**0.33**	**25.65**
Soybeans	52	0.46	22.3	13.2	**0.43**	**28.70**
Sugar Beets	52	0.46	53	36.8	**1.02**	**80.00**

Bluegill sunfish LC50 = 52 ppb
Bluegill sunfish ENEC = 0.46 ppb

Table 7. Acute and chronic RQs for freshwater inverts using maximum application rates with 99% incorporation efficiency (aldicarb TTR).

Crop Use	LC50 (ppb)	NOAEC (ppb)	EEC Initial/Peak (ppb)	EEC 21-day average (ppb)	Acute RQ (EEC/LC50)	Chronic RQ (EEC/NOAEC)
Cotton	20	1	35.1	28.3	**1.75**	**28.30**
Dry Beans	20	1	30.6	26.4	**1.53**	**26.40**
Peanuts	20	1	21.1	15.6	**1.05**	**15.60**
Soybeans	20	1	26.7	20.1	**1.33**	**20.10**
Sugar Beets	20	1	78.0	59.7	**3.90**	**59.70**

Chironomus tentans LC50 = 20 ppb
Mysidopsis bahia NOAEC = 1.0 ppb

Table 8. Acute and chronic RQs for estuarine/marine fish using maximum application rates with 99% incorporation efficiency (aldicarb only).

Crop Use	LC50 (ppb)	NOAEC (ppb)	EEC Initial/Peak (ppb)	EEC 60-day average (ppb)	Acute RQ (EEC/LC50)	Chronic RQ (EEC/ENEC)
Cotton	41	0.36	28.9	19.9	**0.70**	**55.27**
Dry Beans	41	0.36	28.2	21.8	**0.68**	**60.55**
Peanuts	41	0.36	17.4	11.8	**0.42**	**32.77**
Soybeans	41	0.36	22.3	13.2	**0.54**	**36.66**
Sugar Beets	41	0.36	53.0	36.8	**1.29**	**102.22**

Sheepshead minnow LC50 = 41 ppb; Sheepshead minnow ENEC = 0.36 ppb.

Table 9. Acute and chronic RQs for estuarine/marine inverts using maximum application rates with 99% incorporation efficiency (aldicarb TTR).

Crop use	LC50 (ppb)	NOAEC (ppb)	EEC Initial/Peak (ppb)	EEC 21-day average (ppb)	Acute RQ (EEC/LC50)	Chronic RQ (EEC/NOAEC)
Cotton	12	1	35.1	28.3	**2.92**	**28.30**
Dry Beans	12	1	30.6	26.4	**2.55**	**26.40**
Peanuts	12	1	21.1	15.6	**1.76**	**15.60**
Soybeans	12	1	26.7	20.1	**2.22**	**20.10**
Sugar Beets	12	1	78.0	59.7	**6.50**	**59.70**

Pink shrimp LC50 = 12 ppb; *Mysidopsis bahia* NOAEC = 1 ppb.

Even with only 1% of the compound available (99% incorporated), most aquatic organism acute and all chronic RQs calculated exceed LOCs for current uses and are potential risks of concern.

Aquatic Plants

There were no LOC exceedances for aquatic plants.

Terrestrial Animals

In September 2007, the Agency issued a Reregistration Eligibility Decision (RED) for aldicarb (http://www.epa.gov/oppsrrd1/REDs/aldicarb_red.pdf). Key conclusions on exposure and risks to terrestrial and aquatic wildlife as well as relevant data gaps as they relate to these two assessments are listed below. RQs using alternative application rates and incorporation efficiencies (http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2005-0163-0156 and http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2005-0163-0203) were calculated later under addenda to the RED document. These RQs took into account the 99% soil incorporation rates of the specialized application equipment that is used to apply aldicarb. The assessment was updated to reflect current maximum label rates, and the methodology is considered to provide reasonable estimates of potential risks. Risk conclusions remain unchanged from previous assessments. The analysis remains an adequate refined description of the potential risks to terrestrial wildlife.

Tables 10-11 below report the risk quotients for birds and mammals exposed to aldicarb applied at maximum application rates and 99 percent granule incorporation efficiency. This analysis was performed to better characterize risk in the aldicarb ecological risk assessment. The RQs are expressed in terms of LD_{50}/ft^2, which is the current approved risk metric for granular formulations. Conceptually, an LD_{50}/ft^2 is the amount of a pesticide estimated to kill 50% of exposed animals in each square foot of applied area. Although a square foot does not have defined ecological relevance, and any unit area could be used, risk presumably increases as the LD_{50}/ft^2 value increases. The $LD50/ft^2$ value is used to estimate risk for granular formulations and row, banded, and in-furrow applications. For additional information on the LD_{50}/ft^2 risk index, please refer to EPA, 1998.

Table 10. Acute avian RQs for 99 percent incorporation efficiency at maximum application rates.

Crop Scenario	Bird Type	Rate (lbs ai/A)	RQ 99% incorporated
Cotton Banded/Sidedress 4" band width 40" row spacing	Small Bird Medium Bird Large Bird	2.1	220 35 2.7
Dry Beans Banded 6" band width 48" row spacing	Small Bird Medium Bird Large Bird	2.1	175.5 27.6 1.9
Peanuts Banded 6" band width 36" row spacing	Small Bird Medium Bird Large Bird	3.0	160 25 1.8
Pecans Broadcast	Small Bird Medium Bird Large Bird	1.05	104.9 16.5 1.2
Potatoes Banded	Small Bird	3.0	198.5

Table 10. Acute avian RQs for 99 percent incorporation efficiency at maximum application rates.			
Crop Scenario	**Bird Type**	**Rate (lbs ai/A)**	**RQ 99% incorporated**
6" band width 38" row spacing	Medium Bird Large Bird		31.2 2.2
Soybeans Banded 6" band width 30" row spacing	Small Bird Medium Bird Large Bird	3.0	55 9 0.6
Sugar Beets Banded 6" band width 22" row spacing	Small Bird Medium Bird Large Bird	4.95	189.6 29.8 2.1
Sweet Potatoes Banded 12" band width 48" row spacing	Small Bird Medium Bird Large Bird	3.0	124.8 19.6 1.4

Mallard duck LD_{50} = 1 mg/kg- bw.

Table 11. Acute mammalian RQs for 99 percent incorporation efficiency at maximum application rates.			
Crop Scenario	**Mammal Type**	**Rate (lbs ai/A)**	**RQ (99% incorporated)**
Cotton Banded/Sidedress 4" band width 40" row spacing	Small Medium Large	2.1	73 40 4
Dry Beans Banded 6" band width 48" row spacing	Small Medium Large	2.1	59.3 31.4 2.5
Peanuts Banded 6" band width 36" row spacing	Small Medium Large	3.0	32 17 1
Soybeans Banded 6" band width 30" row spacing	Small Medium Large	3.0	19 9.8 0.8
Sugar Beets Banded 6" band width 22" row spacing	Small Medium Large	4.95	64 33.9 2.7
Sweet Potatoes Banded 12" band width 48" row spacing	Small Medium Large	3.0	42.1 22.3 1.8

Rat LD_{50} = 0.9 mg/kg-bw.

Assumptions of incorporation efficiency (Bayer Crop Science and EPA) did not reduce the level of risk to avian and mammalian species below the LOC. The Agency modeled 99% (for banded/sidedress), 99.5% (banded/sidedress and in-furrow) and 99.9% (banded/sidedress and in-furrow) incorporation efficiency at EPA typical application rates (as defined at the time of the RED) to investigate whether such assumptions, albeit unrealistic, would reduce the risk to below LOC for terrestrial wildlife. While some aldicarb granules could still be at the soil surface in spite of attempts to incorporate them into the soil, the 2007 aldicarb RED did suggest that, "due

to the physical properties of aldicarb's granules (e.g., color, size, and solubility)…actual exposure of potentially affected populations to aldicarb granules is uncertain and may be overestimated." Still, none of the modeling scenarios decreased the avian or the mammalian risk below Agency levels of concern for any of the crops, see Tables 12-13. The tables below list the crops, application rates, application methods and RQs for avian and mammalian species.

Table 12. Recalculated acute avian RQs for different incorporation efficiencies at typical application rates with different incorporation efficiencies.

Crop Scenario	Bird Type	Typical Application				
		Rate (lbs ai/A)	RQ 85% incorporated	RQ 99% incorporated	RQ 99.5% incorporated	RQ 99.9% incorporated
Cotton						
Banded/Sidedress	Small Bird	0.6	*947.5*	**60.2**	**30.1**	**6.0**
4" band width	Medium Bird	0.6	*148.9*	**9.5**	**4.7**	**1.1**
40" row spacing	Large Bird	0.6	*10.5*	**0.7**	0.3*	0.7
Dry Beans						
Banded	Small Bird	1.0	*1247.6*	**80.2**	**40.1**	**8.0**
6" band width	Medium Bird	1.0	*196.0*	**12.6**	**6.3**	**1.3**
48" row spacing	Large Bird	1.0	*13.4*	**0.9**	**0.5**	0.09
Peanuts						
Banded	Small Bird	0.9	*842.1*	**54.2**	**27.1**	**5.4**
6" band width	Medium Bird	0.9	*132.2*	**8.5**	**4.3**	**0.9**
36" row spacing	Large Bird	0.9	*9.4*	**0.6**	0.3*	0.06
Soybeans						
Banded	Small Bird	0.7	*545.8*	**35.1**	**17.6**	**3.5**
6" band width	Medium Bird	0.7	*85.8*	**5.5**	**2.8**	**0.6**
30" row spacing	Large Bird	0.7	*6.1*	0.4*	0.2*	0.04
Sugar Beets						
Banded	Small Bird	1.8	*972.1*	**66.2**	**33.1**	**6.6**
6" band width	Medium Bird	1.8	*152.7*	**10.4**	**5.2**	**1.1**
22" row spacing	Large Bird	1.8	*10.8*	**0.7**	0.4*	0.07
Sweet Potatoes						
Banded	Small Bird	1.4	N/A	***58.2***	**28.1**	**5.6**
12" band width	Medium Bird	1.4	N/A	***9.2***	**4.4**	**0.9**
48" row spacing	Large Bird	1.4	N/A	***0.7***	0.3*	0.1**

Mallard duck LD50 = 1 mg/kg- bw
Italicized numbers are RQs published in May 2006 RED; un-italicized represent RQs from new modeling scenarios.
Bold RQs = acute and chronic LOC exceedances for non-listed species; * = restricted use LOC exceedances; ** = listed LOC exceedances

Table 13. Recalculated acute mammalian RQs for different incorporation efficiencies at typical application rates with different incorporation efficiencies.

Crop Scenario	Mammal Type	Typical Application				
		Rate (lbs ai/A)	RQ 85% incorporated	RQ 99% incorporated	RQ 99.5% incorporated	RQ 99.9% incorporated
Cotton						
Banded/Sidedress	Small Mammal	0.6	*320.1*	**21.1**	**10.5**	**2.1**
4" band width	Medium Mammal	0.6	*169.6*	**11.2**	**5.6**	**1.1**
40" row spacing	Large Mammal	0.6	*13.7*	**0.9**	**0.5**	0.09
Dry Beans						
Banded	Small Mammal	1.0	*421.5*	**28.1**	**14.0**	**2.8**
6" band width	Medium Mammal	1.0	*223.3*	**14.9**	**7.4**	**1.5**
48" row spacing	Large Mammal	1.0	*18.1*	**1.2**	**0.6**	0.1**
Peanuts						
Banded	Small Mammal	0.9	*284.5*	**19.0**	**9.5**	**1.9**
6" band width	Medium Mammal	0.9	*150.7*	**10.0**	**5.0**	**1.0**

Table 13. Recalculated acute mammalian RQs for different incorporation efficiencies at typical application rates with different incorporation efficiencies.

Crop Scenario	Mammal Type	Typical Application				
		Rate (lbs ai/A)	RQ 85% incorporated	RQ 99% incorporated	RQ 99.5% incorporated	RQ 99.9% incorporated
36" row spacing	Large Mammal	0.9	*12.2*	**0.8**	0.4*	0.08
Soybeans						
Banded	Small Mammal	0.7	*184.4*	**12.3**	**6.1**	**1.2**
6" band width	Medium Mammal	0.7	*97.7*	**6.5**	**3.3**	**0.7**
30" row spacing	Large Mammal	0.7	*7.9*	**0.5**	0.3*	0.05
Sugar Beets						
Banded	Small Mammal	1.8	*328.4*	**23.2**	**11.6**	**2.3**
6" band width	Medium Mammal	1.8	*174.0*	**12.3**	**6.1**	**1.2**
22" row spacing	Large Mammal	1.8	*14.1*	**1.0**	**0.5**	0.1**
Sweet Potatoes						
Banded	Small Mammal	1.4	N/A	***19.7***	**9.8**	**2.0**
12" band width	Medium Mammal	1.4	N/A	***10.4***	**5.2**	**1.0**
48" row spacing	Large Mammal	1.4	N/A	***0.8***	0.4*	0.08

Rat LD50 = 0.9 mg/kg-bw
Italicized numbers are RQs published in May 2006 RED; un-italicized represent RQs from new modeling scenarios.
Bold RQs = acute and chronic LOC exceedances for non-listed species; * = restricted use LOC exceedances; ** = listed LOC exceedances

Terrestrial Invertebrates

There are expected risks to bees; although aldicarb has granule applications, it is systemic and can be available to bees in plants via pollen and/or nectar. Data gaps prevent a full assessment of risks to bees. See section 4 for additional discussion.

Non-Target Terrestrial Plants

Exposure to non-target plants from spray drift will not occur, because aldicarb is formulated as a granule. Potential adverse effects to non-target terrestrial plants from runoff could not be assessed because of the lack of toxicity data. However, due to the lack of an exposure pathway, no additional data are required at this time.

2. Ecological Incidents

Since the 2016 proposed interim decision was published, the Agency has reviewed the incident databases and updated the reported incident data here. The Ecological Incident Information System (EIIS) was queried on April 30, 2015, and the Incident Data System (IDS) was queried on December 12, 2017. A total of 46 plant and wildlife incidents were in EIIS, 71 domestic animal incidents were in IDS (EIIS does not currently contain information on most of the reported domestic animal incidents), and 283 aggregate incidents have been reported (very little information is reported in aggregate incidents). Many incidents reported in EIIS were associated with intentional poisoning of wildlife, as well as incidents reported in IDS since 2015. Few incidents that occur are observed or reported to the Agency. Therefore, the number of incidents reported is considered to be a very small fraction of the number of incidents that actually occur. Also, incident reports for non-target organisms typically provide information only on mortality events and plant damage. Sublethal effects in organisms such as abnormal behavior, reduced growth and /or impaired reproduction are rarely reported, except for phytotoxic effects in terrestrial plants.

3. Ecological Risk Characterization

The preliminary risk assessment for aldicarb identified RQs that exceeded EPA's LOC for non-listed terrestrial and aquatic animals, and potentially for terrestrial plants. The Agency uses the LOC as an indicator of potential adverse effects to non-target organisms. LOC exceedances are one line of evidence used by EPA to describe the risks posed by a pesticide to non-target organisms. This risk characterization section describes other lines of evidence for aldicarb, puts the LOC exceedances into a broader context, and provides additional perspective on the exceedances.

Since the RED was completed in 2007, the number of aldicarb use sites has decreased: coffee, ornamentals, pecans, sugarcane, sorghum, tobacco, alfalfa grown for seed, citrus, and potato uses were removed from the labels. In addition, the chance of aldicarb granules on the soil surface has been diminished by the agreed upon mitigation to remove the foliar application method on peanuts, remove the T-band application method for all crops, and add label language that specifies the depth that the aldicarb granules must be placed beneath the soil surface. These label changes result in reducing potential runoff of aldicarb to negligible levels, essentially eliminating risk to terrestrial plants and aquatic animals, and reducing the potential for terrestrial animals to encounter and consume aldicarb granules at the soil surface.

Listed Species

Although the Agency is not making a complete endangered species finding at this time and the risk conclusions described in this document pertain to non-listed species; the label changes to address concern for and reduce the presence of granules on the soil surface are also expected to reduce the extent of exposure and may reduce risk to the following listed taxa whose range and/or critical habitat co-occur with the use of aldicarb: terrestrial plants; terrestrial invertebrates; birds; terrestrial and aquatic-phase amphibians; reptiles; mammals; freshwater and marine/estuarine fish and invertebrates.

EPA has not yet fully evaluated risks to listed species at this time. The Agency will complete its endangered species assessment and any necessary consultation with the Services for aldicarb prior to completing the aldicarb registration review.

4. Ecological Effects Data Needs

Since the completion of the proposed interim decision, the Environmental Chemistry Method (ECM) for soil (850.6100) was reviewed and found to be supplemental (EPA, 2017d). Additional information is needed to fulfill the soil ECM/ILV data requirement.

The Agency identified several data gaps for aldicarb in its ecological risk assessment:

- Acute oral toxicity to adult honey bees (non-guideline, tier I)
- Chronic oral toxicity to adult honey bees (non-guideline, tier I)
- Acute oral toxicity to larval honey bees (non-guideline, tier I)
- Chronic oral toxicity to larval honey bees (non-guideline, tier I)

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The Agency will examine the results of the tier I testing, and determine if three additional honeybee studies will be needed:

- Semi-field testing for pollinators (tunnel or colony feeding studies) (non-guideline, tier II)
- Field trial of residues in pollen and nectar (non-guideline, tier II)
- Field testing for pollinators (guideline 850.3040, tier III)

When the registration review docket for aldicarb opened, EPA did not identify the need for any additional studies to evaluate potential effects on pollinators. However, since the issuance of the June 2014 *Guidance for Assessing Pesticide Risks to Bees*[2], EPA has begun to require these data where applicable. EPA intends to issue a DCI to obtain these data, which will inform the pollinator risk assessment.

C. Endangered Species Assessment

In November 2013, the EPA, along with the Services and the USDA, released a summary of their joint Interim Approaches for assessing risks to listed species from pesticides. The Interim Approaches[3] were developed jointly by the agencies in response to the National Academy of Sciences' (NAS) report recommendations, and reflect a common approach to risk assessment shared by the agencies as a way of addressing scientific differences between the EPA and the Services. The NAS report[4] outlines recommendations on specific scientific and technical issues related to the development of pesticide risk assessments that EPA and the Services must conduct in connection with their obligations under the Endangered Species Act (ESA) and FIFRA.

The joint Interim Approaches were released prior to a stakeholder workshop held on November 15, 2013. In addition, the EPA presented the joint Interim Approaches at the December 2013 Pesticide Program Dialogue Committee (PPDC) and State-FIFRA Issues Research and Evaluation Group (SFIREG) meetings. The agencies also held stakeholder workshops - in April and October 2014, in April 2015, and in June 2016 - allowing additional opportunities for stakeholders to comment on the Interim Approaches. Additional workshops are planned to enhance stakeholder involvement. As part of a phased, iterative process for developing the Interim Approaches, the agencies will also consider public comments on the Interim Approaches in connection with the development of upcoming registration review decisions. The details of the joint Interim Approaches are contained in the white paper *Interim Approaches for National-Level Pesticide Endangered Species Act (ESA) Assessments Based on the Recommendations of the National Academy of Sciences April 2013 Report*[5], dated November 1, 2013.

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[2] http://www2.epa.gov/sites/production/files/2014-06/documents/pollinator_risk_assessment_guidance_06_19_14.pdf

[3] *Interim Approaches for National-Level Pesticide Endangered Species Act (ESA) Assessments Based on the Recommendations of the National Academy of Sciences April 2013 Report.* Available at http://www2.epa.gov/endangered-species/interim-approaches-pesticide-endangered-species-act-assessments-based-nas-report

[4] *Assessing Risks to Endangered and Threatened Species from Pesticides*. National Academy of Sciences. 2013. Available from http://www.nap.edu/catalog.php?record_id=18344

[5] Available at https://www.epa.gov/endangered-species/implementing-nas-report-recommendations-ecological-risk-assessment-endangered-and

Given that the agencies are continuing to develop and work toward implementation of the Interim Approaches to assess the potential risks of pesticides to listed species and their designated critical habitat, the ecological risk assessment supporting this Interim Registration Review Decision for aldicarb does not contain a complete ESA analysis that includes effects determinations for specific listed species or designated critical habitat. Although EPA has not yet completed effects determinations for specific species or habitats, for this interim decision, EPA's evaluation assumed, for all taxa of non-target wildlife and plants that listed species and designated critical habitats may be present in the vicinity of the application of aldicarb. This assessment allows EPA to focus its future evaluations on the types of species where the potential for effects exists once the scientific methods being developed by the agencies have been fully vetted. When the Agencies have fully developed and implemented the scientific methodology for evaluating risks for listed species and their designated critical habitats, these methods will be applied to subsequent analyses for aldicarb as part of completing the final registration review decision.

D. Benefits Assessment

Aldicarb is a pesticide with high value to growers because it controls a broad spectrum of pests and has a longer period of residual activity than most alternatives. It also is one of only four currently registered, non-fumigant nematicides on the market for currently labeled aldicarb use sites, making it an important option for growers.

As described below, AgLogic has agreed to mitigation which will increase the drinking water well setback from 50 to 300 feet in Alabama, Georgia, and South Carolina, consistent with the well setback for aldicarb in Florida. The Agency believes this mitigation is necessary to protect human health. However, the longer well setback could impact growers with smaller fields. In these three states, cotton and peanuts are registered uses of aldicarb. The national average and 95th percentile of field sizes for cotton are 17 and 130 acres. The national average and 95th percentile of field sizes for peanuts are 13 and 72 acres. The current 50-foot buffer could restrict the use of aldicarb on up to 0.5 acres and the 300-foot buffer could restrict its use on 6.5 acres around a drinking water well. While this results in an additional 6 acres that could theoretically be affected, drinking water wells are very unlikely to be installed in the middle of a treated field, or at the boundary between two adjacent treated fields. Nonetheless, there is the potential that the longer setback from drinking water wells will reduce the area to which aldicarb can be applied for some fields in these states.

As described in the Proposed Interim Decision, registrant AgLogic has agreed to remove foliar and T-band applications of aldicarb to peanuts. Although the mitigation of removing foliar applications to peanuts also may have some impact on peanut growers, USDA commented that, "We understand that the Agency's interim decision to remove the foliar peanut application, to require changes in application depth for soil-applied granules, and to remove the T-band application method will not be disruptive to pest management strategies."
While alternatives to aldicarb exist, they are not a direct replacement for aldicarb because aldicarb provides effective control of a broad spectrum of pests including nematodes and insects. If growers would not have the option to use aldicarb, then they would have to use multiple chemicals/applications to control the pests that are controlled by a single application of aldicarb. Early season pest control is critical and aldicarb's main value is that a single at-plant application

protects the seedling and young plant for several weeks from attack by plant-parasitic nematodes and insect pests (EPA, 2007a). Aldicarb is generally more cost effective than its alternatives, especially soil fumigant alternatives. Another benefit of aldicarb is that its use on certain crops (e.g., dry beans) results in higher yields (EPA, 2007a).

The use of aldicarb has declined since the 2010 voluntary phase-out decision by Bayer. Bayer's existing stocks have been available on the market, but the available pesticide usage data indicate that the use of aldicarb largely ceased by 2013. Below is a description of the alternatives available for the registered uses of aldicarb. For additional details, see the BEAD memo, *Alternatives Assessment for Aldicarb on Cotton, Dry Beans, Peanuts, Soybeans, Sugar Beets, and Sweet Potatoes* dated December 21, 2016 (EPA, 2016b).

Cotton

The biggest use of aldicarb is on cotton, where it is used primarily for control of nematodes, thrips, and aphids. The key alternatives to aldicarb for thrips and aphid control were thiamethoxam, acephate, and dicrotophos (EPA, 2011a), which were also the top three insecticides used on cotton in recent years (MRD, 2010-2014). However, they only provide thrips control for 3 weeks, compared to 4 or more weeks with aldicarb, or only offer a foliar treatment option and no nematode control (EPA, 2011b). Thiamethoxam, acephate, and dicrotophos are not direct replacements for aldicarb because aldicarb provides a longer efficacious protection and control of both thrips, aphids, and nematodes.

For nematode control, the potential alternatives to aldicarb are soil fumigants including 1,3-D, along with the non-fumigant oxamyl and seed treatments including abamectin. Although the fumigants are effective at nematode control, the pre-plant fumigation has additional restrictions such as buffers around treated fields and the potential use of tarps (EPA, 2007b; EPA, 2014). These fumigant alternatives are much more expensive than aldicarb, and they also do not provide control of thrips. Oxamyl, the other non-fumigant, is mainly a supplemental foliar treatment (UGA, 2016), not a stand-alone alternative to aldicarb as a nematicide. Abamectin was used as a cotton seed treatment on 2.7 million acres on average for the years 2010-2014. This is substantial acreage, but seed treatments are typically not effective against high pest pressure from nematodes.

Dry Beans

Aldicarb is used to control nematodes, seedcorn maggot, and aphids. The use of aldicarb on dry beans is only allowed in Colorado, Oregon, Washington, Idaho, and Michigan. For insect control, alternatives to aldicarb include dimethoate and esfenvalerate. However, these alternatives would likely take at least two foliar sprays against insect pests to provide the same level of protection afforded by an at-plant aldicarb application. For nematode control, aldicarb is an effective non-fumigant and has been recommended by state extensions for use on dry beans (EPA, 2007a). As an alternative to aldicarb for nematode control, a pre-plant fumigant treatment provides no foliar insect control, is cost prohibitive for dry bean nematode control, and has additional use restrictions such as tarps (EPA, 2007a; EPA, 2007b; EPA, 2014). Prior to the 2010 MOA with Bayer, dry bean growers in Michigan used aldicarb on approximately 5% of the crop

in Michigan, and about 30-50% of Treasure Valley growers in Oregon and Idaho used aldicarb on dry beans (EPA, 2007a).

Peanuts

Aldicarb is used on peanuts to control nematodes and thrips and to provide suppression of leafhoppers and spider mites. For insect control, systemic at-plant insecticides such as aldicarb are favored due to their selective nature and to avoid additional pest flare-ups that can occur when using foliar insecticides. Other alternatives for insect control on peanuts include phorate, lambda-cyhalothrin, and acephate. Phorate and acephate are the most widely used at-plant and post-emergence insecticides, respectively, for thrips control, but they do not provide nematode control. Aldicarb has been the leading conventional nematicide used by growers on peanuts. For nematode control, the fumigants chloropicrin, 1,3-D, and metam sodium are recommended and rated to be highly efficacious but have minimal use due to their relatively high cost (EPA, 2011a). Aldicarb has also been used as a later season foliar application to control nematodes, for which there are no effective alternatives yet (EPA, 2006a, EPA, 2007c, EPA, 2016b). Due to the lack of nematicide alternatives and advantages of aldicarb use for both thrips and nematode control, the value and benefits of aldicarb use on peanuts are significant. However, as stated above, aldicarb usage data from 2010-2014 indicate that usage of aldicarb had largely ceased by 2013 and AgLogic did not begin manufacturing aldicarb until 2016. Until other alternatives are registered, growers will need to rely on those methods that they used during that time.

Soybeans

Aldicarb is used on soybean crops to control nematodes, Mexican bean beetle, and thrips. Aldicarb is only allowed to be used on soybeans in Georgia, North Carolina, South Carolina, and Virginia. Aldicarb is considered by industry participants an important chemical for production of soybeans in the southern United States (EPA, 2011b). One alternative to aldicarb for control of soil-borne pests is the fumigant 1,3-D. However, 1,3-D is much more expensive than aldicarb and does not work in no-till programs for soybean production (EPA, 2007a; EPA, 2008). Other alternatives for nematode control include the seed treatments abamectin, *Bacillus firmus*, and *Pasteuria nishizawae*. For thrips control in soybeans the top two insecticides used, imidacloprid and thiamethoxam, were only used as a seed treatment by growers on approximately 7,000 and 220,000 acres, respectively (MRD, 2010-2014). Other alternatives for thrips control include acephate and cyfluthrin. None of the available alternatives provide a direct replacement for aldicarb because aldicarb provides a more efficacious pest control and a broad pest spectrum control against both nematodes and insects.

Sugar Beets

Aldicarb is used on sugar beets to control nematodes, sugar beet root maggot, aphids, leafhoppers, and leafminers. The use of aldicarb on sugar beets is only allowed in California, Colorado, Idaho, Montana, Nebraska, Oregon, Washington, and Wyoming. Alternatives to aldicarb for insect control include terbufos, chlorpyrifos, and phorate. Although the alternatives for root maggot control are less expensive than aldicarb, other considerations make aldicarb a desirable choice. They include the effectiveness of aldicarb against root maggots for control of both adult fly and larvae, and the advantage of aldicarb use targeting both insects and nematodes

with one application. For nematode control, the primary alternative to aldicarb is 1,3-D. However, the cost of 1,3-D per acre is much more than aldicarb and growers need to consider added cost due to different application equipment needed for fumigation. The fumigant metam sodium is available to suppress nematodes but may not provide adequate control, particularly if nematode populations are high (EPA, 2006b).

Sweet Potatoes

Aldicarb is used on sweet potatoes to control nematodes. The use of aldicarb on sweet potatoes is only allowed in Louisiana and Mississippi. Alternatives to aldicarb include the fumigants 1,3-D, metam sodium, and metam potassium. However, their efficacy may be lower than aldicarb, depending on the nematode, and the fumigants are more expensive than aldicarb (EPA, 2007a, EPA, 2006c). Other alternatives to aldicarb include the non-fumigants ethoprop and oxamyl (EPA, 2006c). If nematode populations are low, soils may be treated with oxamyl, and row treatments are less expensive and generally produce better results than broadcast treatments (USDA, 2001). Ethoprop is an organophosphate nematicide listed among control options in the sweet potato crop profiles of Louisiana and Mississippi (USDA, 1999; USDA, 2001).

Use of aldicarb in Louisiana and Mississippi has been small. In Louisiana, approximately 500 acres or less of sweet potatoes were treated with aldicarb for nematode control (EPA, 2007a). In Mississippi, about 800 acres were treated with aldicarb; this is roughly equivalent to 5% of acreage. Although aldicarb has a smaller use on sweet potato than some other crops such as cotton, it was considered by industry experts an important chemical for production of sweet potato slips (EPA, 2011b).

E. Endocrine Disruptor Screening Program

As required by FIFRA and FFDCA, EPA reviews numerous studies to assess potential adverse outcomes from exposure to chemicals. Collectively, these studies include acute, subchronic and chronic toxicity, including assessments of carcinogenicity, neurotoxicity, developmental, reproductive, and general or systemic toxicity. These studies include endpoints which may be susceptible to endocrine influence, including effects on endocrine target organ histopathology, organ weights, estrus cyclicity, sexual maturation, fertility, pregnancy rates, reproductive loss, and sex ratios in offspring. For ecological hazard assessments, EPA evaluates acute tests and chronic studies that assess growth, developmental and reproductive effects in different taxonomic groups. As part of its most recent registration decision for aldicarb, EPA reviewed these data and selected the most sensitive endpoints for relevant risk assessment scenarios from the existing hazard database. However, as required by FFDCA section 408(p), aldicarb is subject to the endocrine screening part of the Endocrine Disruptor Screening Program (EDSP).

EPA has developed the EDSP to determine whether certain substances (including pesticide active and other ingredients) may have an effect in humans or wildlife similar to an effect produced by a "naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." The EDSP employs a two-tiered approach to making the statutorily required determinations. Tier 1 consists of a battery of 11 screening assays to identify the potential of a chemical substance to interact with the estrogen, androgen, or thyroid (E, A, or T) hormonal systems. Chemicals that go through Tier 1 screening and are found to have the potential to

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interact with E, A, or T hormonal systems will proceed to the next stage of the EDSP where EPA will determine which, if any, of the Tier 2 tests are necessary based on the available data. Tier 2 testing is designed to identify any adverse endocrine-related effects caused by the substance, and establish a dose-response relationship between the dose and the E, A, or T effect.

Under FFDCA section 408(p), the Agency must screen all pesticide chemicals. Between October 2009 and February 2010, EPA issued test orders/DCIs for the first group of 67 chemicals, which contains 58 pesticide active ingredients and 9 inert ingredients. A second list of chemicals identified for EDSP screening was published on June 14, 2013[6] and includes some pesticides scheduled for registration review and chemicals found in water. Neither of these lists should be construed as a list of known or likely endocrine disruptors. Aldicarb is not on list 1 or list 2. Initially aldicarb appeared on list 1, but it was removed from the list because changes in its use and application methods eliminated the potential for exposure in one or more pathways. A reassessment of aldicarb's uses confirmed that it would only be expected to be present in two, instead of three, exposure pathways (i.e., the criterion for selecting chemicals for the initial list (List 1) was the presence of the chemical in at least three of the four exposure pathways where the food and occupational exposure pathways were represented). For further information on the status of the EDSP, the policies and procedures, the lists of chemicals, future lists, the test guidelines and the Tier 1 screening battery, please visit our website.[7]

In this interim decision, EPA is making no human health or environmental safety findings associated with the EDSP screening of aldicarb. Before competing this Registration Review, the Agency will make an EDSP FFDCA section 408(p) determination.

IV. REGULATORY RATIONALE AND INTERIM REGISTRATION REVIEW DECISION

A. Risk Mitigation Measures

As discussed in Section III of this document, aldicarb poses potential dietary risk concerns, human health concerns for handlers, and potential ecological risk to non-listed terrestrial and aquatic animals, and terrestrial plants. In evaluating potential risk mitigation for aldicarb, EPA considered the risks, the benefits, and the use pattern of this compound. For the human health and ecological risks identified, the Agency is requiring mitigation that will reduce the risks. The potential ecological risks, which are reduced with the mitigation, are outweighed by the benefits associated with use of this compound.

Information received in public comments and additional data submitted to the Agency have resulted in some revisions from the Proposed Interim Decision and are included in this document. Mitigation measures proposed by the registrant during the public comment period for the draft risk assessments (DRAs) are expected to reduce the acute drinking water exposure estimates from surface water contributions. Longer well setbacks in the southeast United States, in states where monitoring data suggested the need, are expected to reduce drinking water

[6] See http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPPT-2009-0477-0074 for the final second list of chemicals.
[7] http://www.epa.gov/endo/

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exposure from groundwater contributions. In addition, EPA received and verified refined domestic percent crop treated (PCT) information for sweet potatoes, and percent of imported commodity in domestic consumption for oranges, orange juice, and potatoes. The revised information resulted in an increase of the acute dietary (food only) exposure estimates, but the food only estimates remain below EPA's level of concern (LOC) for the U.S. population and all population subgroups.

EPA does not have dermal absorption data available for aldicarb and, to address potential risks of concern to handlers, requested either aldicarb-specific dermal absorption data or bridging data from other carbamates during the public comment period for the proposed interim decision. Neither dermal absorption data nor bridging data were submitted during the comment period. However, the Agency received comments that the actual acres of sugar beets treated in a given day and the documented half-life of aldicarb cholinesterase inhibition in the human body as a result of the reversibility of effects are the two most important considerations when determining the risk associated with worker exposure to aldicarb during application to sugar beets. The Agency received comments describing the actual acres of sugar beets treated in a given day and detailed information about sugar beet applications to consider. This information helped to refine the risk assessment and reduce the predicted exposure. Details are described below.

1. Human Health

Dietary – Drinking Water

The Agency described its assessment of potential exposure to aldicarb in drinking water in the June 17, 2015 document, *Aldicarb: Drinking Water Exposure Assessment for Preliminary Risk Assessment.* This assessment recommended that the human health dietary assessment use an EDWC of 187 ppb of total aldicarb residues for acute exposures, and an EDWC of 40 ppb of total aldicarb residues for chronic exposures. The acute EDWC was simulated for surface water exposure using the SWCC, and the chronic EDWC was simulated for ground water exposure using the PRZM-GW model. Use of the surface-water EDWC resulted in risk estimates above the level of concern, 2,900% of the aPAD.

After reading the Draft Risk Assessments (DRAs) and providing public comment, the registrants offered additional mitigation measures to reduce the potential for aldicarb exposure in drinking water. The acute EDWC was calculated by simulation of the highest rate for sugar beets that can be applied without soil cover, which significantly increases the risks of surface water exposure. Most labels required that aldicarb granules applied to sugar beets be covered with soil, or incorporated to a certain depth. Registrants offered to change aldicarb labels to ensure all uses required granules to be incorporated at specific depths. They also offered to remove label instructions allowing foliar application to peanuts, and to eliminate T-band applications (which distribute granules evenly from the bottom of a furrow up to the surface) for all crops. Granules that are at or near the surface could result in aldicarb transport in water to surface water drinking water sources, and removing these application methods reduces the potential for this to occur.

As a result of these commitments to change the label, the concern for drinking water exposure through contamination of surface-water sources would be addressed once the mitigation proposals are implemented. The SWCC only considers pesticide residues present in the top 2 cm

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of the soil profile to be available for runoff. This was based on calibration of the runoff model to field studies available at the time the policy was developed. Therefore, the proposed mitigation would reduce the EDWCs for surface water to zero.

Both the acute and chronic EDWCs for aldicarb were then derived for groundwater sources using PRZM-GW simulations. PRZM-GW simulates one-dimensional movement of water and pesticide residues from the surface through highly vulnerable sandy soil to a water table 10 to 30 feet below the surface. Six different scenarios are simulated by the model, representing the soils and weather of locations in Wisconsin, the Delmarva Peninsula, North Carolina, Georgia, and Florida (two scenarios). The highest acute EDWC derived was from the Florida Central Ridge scenario, at 93 ppb. Simulations were run to represent soil pH values of 6, 7 and 8, because the hydrolysis of aldicarb is pH dependent. The EDWC of 93 ppb represents the Florida Central Ridge scenario under pH 6 conditions, because aldicarb hydrolyzes most slowly at that pH among the three pH conditions simulated. In Table 14 below, which provides estimates of total toxic residues of aldicarb (TTR), concentrations are significantly less under more alkaline conditions, and show a range of more than an order of magnitude across the six highly vulnerable scenarios.

Table 14. PRZM-GW Output for Aldicarb TTR[A].

Use Crop	Modeled Scenario (ID, OR, WA)	Well Setback (ft)	Groundwater pH	Max. Daily Conc. (µg/L)	Mean Break-through Time (yrs)	Post-breakthrough Mean (µg/L)
Sugar Beets	DELMARVA	50	6	54	5.5	33
			7	9.3		3.5
			8	3.8E-03		2.7E-05
	FL Central Ridge	50	6	**93.2**	3.4	**40**
			7	**33.6**		**5.8**
			8	**1.62**		**3.3E-03**
	FL Jacksonville	50	6	53	2.7	25
			7	15.1		4.2
			8	1.09		3.0E-03
	GA Southern Coastal Plain	50	6	6.6	5.4	2.5
			7	0.46		0.06
			8	2.0E-07		5.8E-10
	NC Eastern Coastal Plain	50	6	4.2	9.0	2.6
			7	0.26		0.08
			8	8.84E-05		5.9E-07
	WI Central Sands	50	6	21	**11.9**	15.9
			7	0.85		0.43
			8	1.0E-06		1.9E-08

[A] Maximum values are in bold.

Representativeness of PRZM-GW scenarios

The October 23, 2006 document, *Drinking Water Exposure Assessment for Total Aldicarb Residues (Parent, Aldicarb Sulfoxide, and Aldicarb Sulfone) Based on the N-Methyl Carbamate*

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Cumulative Risk Assessment, points out that the groundwater exposure simulated by PRZM-GW represents private drinking water wells. In general, public water supplies supplied by groundwater will typically draw from deeper aquifers and/or aquifers that have a relatively impermeable layer between the surface and the water supply. Such supplies are expected to be much less vulnerable to pesticide contamination. Public water supplies have a higher probability of being treated, although conventional treatments processes are likely to result in little or no reduction of aldicarb residues in water. However, where lime softening, which will accelerate pH-dependent hydrolysis for aldicarb sulfoxide and sulfone, or activated carbon filtration is used, some reduction in aldicarb residues between untreated and treated water may occur.

The 2006 assessment used PRZM to compare estimated concentrations from wells drawing from 15, 30, and 50 feet. The 30-50 foot depths are more representative of shallow private wells, while the 15-foot depth may represent shallow dug wells. With the increased travel time allowing for more degradation, estimated aldicarb residues decreased by nearly an order of magnitude between 15 and 30 feet. Estimated concentrations at 50 feet were approximately 3 times lower than those at 30 feet. This suggests that risk from potential exposure to aldicarb from groundwater sources would be less in areas where drinking water is drawn from greater depths. Table 14 above from the 2015 drinking-water assessment shows the difference with depth, as well. The highest EDWCs are from the Florida Central Ridge scenario, which simulates a 10-foot deep water table. All of the other scenarios have lower concentrations, and all of them simulate well screens drawing from the top of a 30-foot deep water table.

In the most recent, 2015 drinking-water assessment cited above, the Agency stated the scenarios used in PRZM-GW were suitable surrogates to represent vulnerable soils: "PRZM-GW scenarios and soil types were developed and simulated as proxies with a conservative approach to best represent the most vulnerable soils with high leaching potential and shallow groundwater table in order to account for groundwater contamination risks." However, in their comments on the draft risk assessments, the registrant pointed out that use in the areas simulated by PRZM-GW were either not allowed on the current aldicarb labels, or represented areas where labelled aldicarb crops would not be grown. For instance, the PRZM-GW scenarios which resulted in the highest EDWCs were run using the application rate and directions for sugar beets, although the labels do not allow application of aldicarb to sugar beets in the five states represented in the scenarios.

The use of this screening-level acute EDWC resulted in risk estimates above the level of concern, and so it is appropriate to further explore to what extent the modeled scenarios are representative of actual aldicarb use areas allowed on the label. For instance, the areas in which aldicarb can legally be used on sugar beets (WA, OR, CO, ID and NE) receive significantly less rain than the Florida scenario which produced the highest EDWCs. In addition, the 2006 drinking water assessment provided this additional characterization:

> "In other regions of the country, anticipated exposure to aldicarb residues in groundwater is expected to be lower than estimated in these scenarios or in surface water scenarios representing those regions. In the north and north-central, groundwater exposures are expected to be lower because of low use or because aldicarb is no longer labeled for use, particularly in northeastern states where acidic conditions and high leaching potential conditions exist. In the mid-south, drinking water is drawn predominantly from public ground water supply from

deep, protected aquifers and aldicarb contamination is not expected. In the Great Plains and lower Midwest, anticipated exposure is expected to be lower because of low rainfall and deeper aquifers than in the southeast and Florida. In many parts of the west, alkaline soils and/or ground water will also facilitate the rapid breakdown of aldicarb residues into non-toxic degradation products."

In addition to being conservative as surrogates, the six scenarios as run above overstate potential exposure in the areas they simulate. For instance, current aldicarb labels do not allow application in Delaware, Maryland, or Wisconsin. Application is allowed in the other states, although aldicarb was historically used on citrus in the Central Ridge of Florida, and use on citrus is no longer allowed. In addition, aldicarb labels require much greater well setbacks for vulnerable soils in these states. These setbacks include a 300-foot setback in North Carolina and Virginia, a 700-foot setback in Florida, and up to a 1,100-foot setback in Georgia. As shown in PRZM-GW outputs below (Table 15), this has a significant effect on EDWCs, even when considering the slow hydrolysis at pH 6. Values shown are for the Florida Central Ridge for aldicarb residues only:

Table 15. PRZM-GW outputs for Florida central ridge.

Well Setback (ft)	Max. Daily Conc. (µg/L)	Post-breakthrough Mean (µg/L)
50	79.61	24.68
300	25.46	7.89
500	10.23	3.17
700	4.11	1.27
1,000	1.05	0.32

Soils in the Florida Central Ridge are mainly derived from limestone, and would be slightly alkaline. If the simulation were done using a shorter, alkaline hydrolysis half-life, the predicted concentrations would be lower than those shown above.

Consideration of well setbacks and different ground-water velocities

The effects of the setback distances are simulated in the PRZM-GW by assuming the peak concentration simulated in the well, and then having that groundwater move laterally through the setback distance to another drinking water well directly downgradient. Because the transport from beneath the treated field to a well some distance away takes time, further hydrolysis of aldicarb residues will reduce the concentration by the time it reaches the well.

When exploring the effect of well setbacks, Agency policy states that the assessment will first evaluate potential reductions under conditions with a quick lateral groundwater velocity of 1.0 ft/day. This rate of movement is conservative, but reasonable, for sandy soils such as those represented in the six PRZM-GW scenarios. The velocity of ground water in soils with a greater percentage of clay would likely be significantly slower, possibly by orders of magnitude. In addition, pH of soils in the aldicarb use will have direct bearing on the effectiveness of drinking water well setbacks. While a range of pH values is possible in any area, alkaline soils are more prevalent in arid areas, and more acid soils more common in with greater rainfall and wetter soils. The 2006 drinking water assessment added that because "travel time varies with well

depth, a longer setback distance would be needed for shallower wells while a shorter setback distance might be sufficient for deeper wells."

The regionally differential susceptibility of groundwater drinking water sources to aldicarb contamination is reflected by the number of states in which aldicarb use is not allowed, and in the different setback distances required in different states in which use is allowed on the aldicarb label. For instance, in some southeastern states, use on vulnerable soils with shallow water tables similar to those simulated in PRZM-GW requires well setbacks as long as 1,100 feet. By contrast, some use areas such as the Northwest, which generally have more alkaline soils and ground water, and deeper water tables, a 50-foot well setback was determined to be sufficient.

To better characterize the potential risk on a nationwide scale, the Agency simulated possible shallow groundwater concentrations of aldicarb for different setback distances assuming a lateral flow velocity less than the conservative 1.0 ft/day in the direction of a drinking water well. For pH 7 conditions, under which the hydrolysis half-life of aldicarb is 63 days, the effects of well setback at different distances are as follows, assuming a more typical lateral flow velocity of 0.1 ft/day, Table 16:

Table 16. Effects of well setbacks at different distances (lateral flow velocity of 0.1 ft/day)

Well Setback (ft)	Max. Daily Conc. (µg/L)	Post-breakthrough Mean (µg/L)
0	33	3.5
50	0.134	0.0142
300	1.53E-13	1.62E-14

The Agency believes that the well setbacks currently in effect are sufficient to protect against dietary risk from drinking water exposure for the majority of the areas on aldicarb labels. Aldicarb use is either explicitly disallowed in certain vulnerable areas, as in Wisconsin, or on certain crops that were grown in very vulnerable areas, such as citrus on the Central Ridge of Florida. In highly vulnerable areas of the Southeast where acidic, sandy soils overlay shallow water tables, extensive well setbacks of 300 to 1,100 feet protect drinking-water wells from problematic aldicarb contamination, especially because only a fraction of such wells will be directly downgradient from a treated field.

For the limited use areas in the rest of the country, a number of different conditions justify the continued imposition of shorter well setbacks. These areas generally have less rainfall than the Southeast. Soils will not be as uniformly sandy as the Atlantic coastal plain as a whole, are less likely to be acidic, will more often have greater depths to the water table, and should have lateral groundwater velocities less than the 1.0 ft/day simulated by PRZM-GW at the screening level. However, while it is not possible to simulate every set of conditions that may occur, it is possible that there are small parts of the aldicarb use area that are similarly vulnerable to those simulated by PRZM-GW. The Agency requested information about such aldicarb use areas during the public comment period for the proposed interim decision.

The Agency received public comments on the proposed interim decision from AgLogic. AgLogic commented that it is more appropriate to use water monitoring data than PRZM-GW modeling and cited a 2005 Bayer CropScience retrospective groundwater monitoring study as

providing critical information on measured aldicarb residues in drinking water wells in selected areas of the United States following actual product use by farmers. The Agency reviewed the 2005 study; it identified various wells in the southeast United States where combined aldicarb residues are above OPP's current level of concern (0.87 ppb) and may indicate potential risks of concern.

The Agency cross-walked current mitigation on the aldicarb product label (put in place following the 2007 RED) for wells where combined aldicarb residues detected ranged from 0.86 – 2.90 ppb to check if any of the wells could have aldicarb levels of concern today. The conditions for several wells would only require a 50-foot well setback which may not be protective when aldicarb residues are 0.87 ppb or higher (Table 17).

Table 17. Groundwater wells of potential concern today

Site	Crops Grown	Combined Aldicarb Residues (ppb)	Well Setback Based on Current Label (ft)
Alabama 1	cotton	1.77	50
Alabama 2	cotton	0.86*	50
Alabama 3	cotton and peanuts	1.21	50
Georgia 1	cotton and peanuts	2.9	50
South Carolina 1	cotton and peanuts	0.89	50

* Average value – one individual sample at this well was greater than 0.87 ppb.

Even though aldicarb application rates have been lowered and some application methods are no longer in use since the study was conducted in 2005, the Agency is concerned that current mitigation would not be protective for the region in which those drinking water wells were located. The Agency acknowledges that there are uncertainties associated with the 2005 data (i.e., application rate, application method), but the data present actual concentrations of aldicarb measured in drinking water wells in 2005 (EPA, 2017e).

The Agency interprets these results as indicating the need for localized mitigation in the southeast United States. Because the data included some wells in less vulnerable soils, the Agency concludes that this justifies an increase in the minimum well setback distance in all soils in Alabama, Georgia, and South Carolina to allow more time for aldicarb and its metabolites to degrade as it moves through the soil. EPA is requiring an increase in the minimum well setback distance from 50-feet to 300-feet in non-vulnerable soils in Alabama, Georgia, and South Carolina, similar to the requirements already in place in Florida (see section 5E-2.028 of the Florida Administrative Code), to ensure groundwater concentrations of aldicarb remain below the DWLOC. The additional well setback distance in combination with lower use rates and different use patterns/application methods that are on the current label will protect drinking water resources in the southeast United States.

After the Agency discussed these concerns with AgLogic, AgLogic commented:

> "AgLogic is not convinced that the Temik brand aldicarb applications that led to the exceedances in the five drinking water wells represent current practices for the following reasons:
> - Aldicarb rates have been lowered 50% for peanuts and 60-65% for cotton since the 2005 study was performed.

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- AgLogic has made label changes in which 'over the top' (non-incorporated) applications are no longer allowed on peanuts.
- The 2005 study which is not in our possession was a retrospective monitoring study, in which to our knowledge, there was no verification done to ensure that Temik brand aldicarb applications strictly followed label provisions making it impossible to determine if the results were a potential aberration due to broadcast applications followed by torrential rains, equipment problems, poor handling, sloppy application practices, or the result of point source contamination from cleaning application equipment too close to the drinking water wells.

AgLogic Chemical, LLC and their customers are very strongly committed to being good stewards of aldicarb. Our Product Stewardship programs are an industry standard aimed to educate and to limit users to those committed to prevent misuse. We want to ensure that the use patterns on AgLogics aldicarb product labeling are protective of drinking water wells. While for the reasons we have outlined, we believe the current labeled drinking water well setback buffer zones are sufficiently protective, we nonetheless agree to the proposed 300-foot well setback buffer zones in the states of Alabama, Georgia, and South Carolina, regardless of the vulnerability of the soil, as we recognize that absent directed setback studies, these more restrictive drinking water well setback buffer zones will further decrease the remote possibility of ground water contamination by aldicarb."

Dietary – Food

A highly refined acute dietary (food only) exposure assessment was conducted in March 2016 using the Dietary Exposure Evaluation Model (DEEM-FCID™, Version 2.03) for all existing food uses of aldicarb (EPA, 2016a). During the public comment period for the PID, information was received from the governments of Costa Rica and Mexico regarding the use of aldicarb in those countries and EPA revised the percent crop treated estimates with that information (EPA, 2017a). The new estimates were incorporated into a revised dietary (food only) exposure assessment in November 2017 (EPA, 2017b). In the revised assessment, estimated acute dietary (food only) exposure and risk estimates remain below EPA's level of concern (LOC) for the U.S. population and all population subgroups. Food only exposure is equivalent to 27% of the acute population adjusted dose (aPAD) at the 99.9th percentile of exposure for the general U.S. population and 74% of the aPAD for the highest exposed population subgroup, children 1-2 years old.

A commodity specific analysis (CSA) was conducted for aldicarb in March 2016 to obtain estimates of the acute exposure and risk following a single consumption event for registered uses of aldicarb. The CSA considers the potential acute exposure and risk following a single consumption event of a specific commodity, were that commodity to contain aldicarb residues equal to the highest concentration measured over years of measurements.

Dietary exposures were calculated using typical serving sizes for amounts consumed and USDA Pesticide Data Program (PDP) monitoring data. While aldicarb is no longer used domestically on

certain commodities (e.g., potatoes), tolerances remain in place which allow import into the U.S. These imported commodities may contain aldicarb residues. Dietary exposures were expressed as a percent of the aPAD (0.00027 mg/kg/day). The 2016 CSA resulted in exposure estimates above 100% of the aPAD following consumption of an estimated single serving of sweet potato and potatoes. The highest percent of the aPAD were for pre-school age children eating the equivalent of one average size potato (130% aPAD) or sweet potato (300% aPAD). A similar analysis performed for other crops to which aldicarb can be applied did not result in estimated exposures that would exceed the LOC.

The CSA for potato was removed from the 2017 revised dietary exposure assessment (EPA, 2017b) because new information indicates that aldicarb-treated fresh potatoes are not imported to the United States and there is no domestic aldicarb use on potato. However, the revised dietary exposure assessment still presents exposure estimates above 100% of the aPAD for a preschool child following consumption of one medium-sized baked sweet potato. The risks identified by CSA should be considered to represent rare consumption events and these estimates represent exposures beyond the 99.9th percentile considered as the point of regulation for the Agency's distributional human health dietary risk assessments in cases where percent crop treated data are used.

Sweet Potato

The most recent PDP monitoring data (2008-2010) for sweet potatoes identified two detects at 0.07784 ppm and 0.06894 ppm out of 1,476 samples of unpeeled sweet potato, that are above the threshold (i.e., residue level that would result in risk at the LOC) for preschoolers (0.026 ppm). This is approximately 0.14% of the samples above the threshold. The dietary exposure is above EPA's LOC (i.e., >100% of the aPAD) for preschoolers consuming one medium size sweet potato (157 g) (300% of the aPAD). The estimated exposure assumed that a preschooler consumed a medium-sized, baked sweet potato, with no processing factors to reduce the potential exposure. Processing factors are available for boiled, canned-cooked, canned-boiled and fried sweet potatoes, but not for baked sweet potatoes. Exposures are below the LOC for adults consuming one medium size sweet potato (75% of the aPAD).

Also, the most recent PDP monitoring data (2010-2011) for sweet potato baby food identified no detects above the limit of detection of 0.0083 ppm out of 776 samples taken. This results in exposures below the LOC for infants (24% of the aPAD).

For the two sweet potato samples above the threshold, both were sampled in Texas, with one sample packed in North Carolina, but there is no information on where the other sample was packed. In 2016 and 2017, PDP monitored for residues of aldicarb in sweet potatoes. However, that data have not been published yet.

In 2010, aldicarb could be used nationally on sweet potatoes. In August of 2010 EPA and Bayer CropScience entered into an agreement that restricts the use of aldicarb to two states, Louisiana and Mississippi. According to U.S. Census of Agricultural data, Louisiana and Mississippi sweet potato acreage ranges from 25% to 34% of total U.S. acreage. Use of aldicarb in Louisiana and Mississippi is low. In Louisiana, approximately 500 acres or less of sweet potatoes were treated with aldicarb for nematode control (EPA, 2007a). In Mississippi, about 800 acres were treated

with aldicarb; this is roughly equivalent to 5% of acreage. This suggests that in the future, the overall percentage of sweet potatoes with aldicarb residues at any level should be significantly less than when the 2008-2010 PDP monitoring data were collected. Given that the CSA represents exposures beyond the 99.9th percentile considered as the point of regulation for the Agency's distributional human health dietary risk assessments in cases where percent crop treated data are used and that the use area has been reduced to two states since these samples were taken, the Agency has concluded that there are no dietary risks of concern.

Occupational: Handlers

As discussed in Section 3 above, there were two occupational handler risk estimates of concern for mixing and loading aldicarb using open pour systems for sugar beets at the application rates of 3 lb ai/acre and 4.95 lb ai/acre. The combined dermal and inhalation LOC is 10 and the MOE in the 2016 occupational assessment was 7.4 for the 3 lb ai/acre application rate and 4.5 for the 4.95 lb ai/acre application rate. These two scenarios assume open pour/open cab application scenarios, using chemical-specific unit exposure data and the use of label required PPE (i.e., a double layer of clothing and a standard filtering face-piece respirator). This risk concern is a combined risk estimate (dermal + inhalation) that is driven by dermal exposure. The inhalation component is already above the LOC.

Even though PHED data were presented in the preliminary risk assessment, the Agency believes that the chemical-specific data is more appropriate in this instance and those are the only data presented in this document.

The registrant submitted information about aldicarb applications to sugar beets. In the 2007 occupational assessment, an assumption of 80 acres per day was used, and in the 2016 assessment, 200 acres per day was used. The registrant believes that 80 acres treated a day for a typical field crop would be a more reasonable number and provided supporting information for this claim. The Agency reviewed the information submitted and also separately analyzed sugar beet practices. The Agency determined that 50 to 105 acres of sugar beets could be planted per 8-hour workday depending on the application equipment used (EPA, 2017c). Incorporating the more conservative value of 105 acres into the occupational assessment yields the following revised mixer/loader risk estimates for the use of aldicarb on sugar beets as summarized in Table 3 in Section 3 above. At the maximum rate of 4.95 lb ai/A (used for nematode control), the MOE is 8.5 and at the rate of 3 lb ai/A (used for control of other pests listed on the label), the MOE is 14.

While it is possible for a mixer/loader to be exposed to the entire amount handled once per day, the Agency acknowledges that it is likely that the full amount of product is not loaded in one event per day; therefore, multiple mixing/loading events could be considered and inclusion of the aldicarb cholinesterase inhibition half-life into the occupational assessment could be a reasonable refinement. Using the revised acreage listed above (i.e., 105 acres) split into two events separated by 2 hours, and including the aldicarb cholinesterase inhibition half-life, the MOE for mixing/loading granules for sugar beets at the maximum application rate of 4.95 lb ai/A is 11 with a LOC of 10. When considering these risk estimates, the following points are also acknowledged by the Agency:

- The 105-acre/day estimate is considered high-end for at-plant tractor granule herbicide applications. If 50 acres had been used as an assumption for the number of acres treated in an 8-hour workday, there would be no risks of concern for all application rates.
- Information regarding the flux rate of aldicarb through the skin is not available, therefore, the calculation assumes immediate absorption through the skin.

It also should be noted that an assumption of 100% dermal absorption was used in the dermal exposure/risk calculations since an acceptable dermal absorption study was not submitted for aldicarb. The two registered aldicarb products are granular products with a concentration of 15% active ingredient, which have either a corn cob grit or vinyl-coated gypsum-based substrate, and are considered low-dust formulations. Given that the registered products are a granular formulation and considered low dust formulations, it is unlikely that 100% dermal absorption would occur.

The Agency has evaluated the alternatives of aldicarb for nematode control in sugar beet production areas. The use of aldicarb on sugar beets is only permitted in California, Colorado, Idaho, Montana, Nebraska, Oregon, Washington, and Wyoming. For nematode control, the primary alternative to aldicarb is 1,3-D. However, the cost of 1,3-D per acre is much more than aldicarb and growers need to consider added cost due to different application equipment needed for fumigation. The fumigant metam sodium is available to suppress nematodes but may not provide adequate control, particularly if nematode populations are high (EPA, 2006b). The Agency believes that the benefits of aldicarb use on sugar beets for nematode control are high.

2. Ecological

Potential acute risks from ingestion and exposure through runoff were identified for non-listed aquatic and terrestrial animals, along with potential risks to terrestrial plants.

Ingestion and Runoff Exposure

There are risks to terrestrial animals from aldicarb granules on the soil surface. The ingestion of only one granule can lead to mortality. However, while birds might ingest granules along with pebbles or grit they consume to aid digestion, mammals do not have a clear reason to purposely consume the granules. Consumption of whole granules or partially dissolved granules might occur inadvertently in mammals foraging in the soil.

In addition to risks from ingestion, runoff is another route of exposure that can potentially lead to risks of concern for aldicarb in animals. Aldicarb is soluble in water, poorly sorbed on soil particles and could expose birds and mammals to dissolved granules after application in drinking water puddles after a rain or an irrigation event occurs. If that occurs, wildlife species are likely to be killed from drinking contaminated water from treated fields after rain. Drinking water exposure alone was determined to be a potential acute and chronic pathway of concern for avian and mammalian species. To address risk from ingestion and runoff, the technical registrant has agreed to the following mitigation for aldicarb products to reduce the number of available granules at the soil surface and thereby eliminate ingestion of granules on the surface and exposure to dissolved granules in drinking water puddles after rain or irrigation occurs.

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- Remove foliar applications on peanuts
- Remove T-band applications for all crops
- Specify the depth that aldicarb granules must be placed beneath the soil surface

By restricting application of aldicarb to a depth that eliminates runoff from a treated field, the Agency no longer expects exposure or risk to terrestrial and aquatic plants, or to aquatic animals.

Pollinator Advisory Language

The protection of pollinating organisms is a priority for the Agency. Currently available evidence does not suggest that using aldicarb directly impedes the health of pollinators. However, it is possible that aldicarb applications could negatively impact pollinators through contact with plants (via pollen and nectar) due to aldicarb's systemic nature. At this time the Agency is not intending to add pollinator advisory language to the product labels for the following reasons: (i) the application method reduced the potential exposure pathway (for honey bees) to dietary only and the Agency does not have any pollinator data for the oral route of exposure; (ii) the application method does not result in drift. EPA intends to issue a DCI to obtain pollinator data, which will inform the pollinator risk assessment. If the data indicate that pollinator advisory language is needed, it will be required in the future.

Appendix C contains a complete list of all the required label changes for aldicarb.

B. Insecticide Resistance Management

Pesticide resistance may occur when genetic or behavioral changes enable a portion of a plant pest populations (such as bacteria, fungi, insects or other organisms) to tolerate or survive what would otherwise be lethal doses of a pesticide. The surviving pest populations increase with continued exposure to a no longer effective pesticide. Resistance to pesticides by plant pest appears to be increasing in the U.S. and worldwide. Managing the evolution of pesticide resistance in plant pests is an important part of sustainable pest management and an integral part of IPM programs, to assist crop producers to manage plant pests effectively.

The development of pesticide resistance is influenced by a number of factors. One important factor that fosters pesticide resistance is the repeated use of pesticides with the same mode of action on the same pest population. Repeated use of a pesticide with a single mode of action kills sensitive pests but allows pests in the population that are tolerant of the pesticide to increase in numbers. These individuals will generally be unaffected by the repeated pesticide applications and may ultimately make-up a substantial portion of the pest population. Thus, an important proactive pesticide resistance-management strategy is to rotate pesticides with different modes of action to increase the likelihood of controlling of target pests in any given location or area. This approach may delay and/or prevent the development of resistance to a particular mode of action without resorting to increased rates and frequency of application, and may prolong the useful life of pesticides. EPA is requiring resistance-management labeling, as referenced in Appendix C, for products containing the insecticide aldicarb, in order to provide pesticide users with easy access to important information to help maintain the effectiveness of useful pesticides. Additional information on EPA's guidance for resistance management can be found at the following website: https://www.epa.gov/pesticide-registration/pesticide-registration-notices-year.

C. Tolerance Amendments

Tolerances are established in the 40 CFR § 180.269 for the use of aldicarb on bean, sugar beet, coffee, cotton, grapefruit, lemon, lime, orange, peanut, pecan, potato, soybean, sugarcane and sweet potato. These tolerances are based on measurement of combined residues of aldicarb and its cholinesterase-inhibiting metabolites aldicarb sulfoxide [2-methyl-2-(methylsulfinyl) propionaldehyde O-(methyl carbamoyl) oxime] and aldicarb sulfone [2-methyl-2-(methylsulfonyl) propionaldehyde O-(methyl carbamoyl) oxime] and range from 0.02 to 1 ppm. The tolerances for dry bean, sugar beet, cotton, peanut, soybean and sweet potato are based on domestic uses of aldicarb. Although tolerances for potato, citrus, coffee, pecan, and sugar cane are established in the CFR, there are no registered uses in the U.S. EPA recommends adding a footnote clarifying this registration status. Livestock feedstuffs are associated with uses of aldicarb, but tolerances are not established for livestock commodities because transfer of residues to livestock commodities is not expected (i.e., a 40 CFR §180.6(a)(3) situation applies).

The U.S. tolerance definition is harmonized with the maximum residue limit (MRL) definitions for Canada and Codex: the residues of concern are aldicarb, aldicarb sulfoxide, and aldicarb sulfone. U.S. tolerances and MRLs (Canadian and Codex) are harmonized except for citrus fruits, cotton, peanut, pecan, potato, and sugarcane. Increasing the U.S. tolerances for pecan and sugarcane to 1.0 and 0.10 ppm, respectively, will result in harmonization with Codex MRLs. Differences in good agricultural practices preclude harmonization of tolerances and MRLs for the remaining crops where differences are noted.

EPA recommends the following tolerance changes for aldicarb based on the residue chemistry database, see Table 18:

Table 18. Recommended aldicarb tolerance changes.

RAC	Current Tolerance (ppm)	Recommended Tolerance (ppm)	Comment
Beet, sugar, tops	1	Revoke	Not a significant livestock feed item.
Cotton, undelinted seed	0.10	0.20	Based on data provided in MRID 48156901.
Cotton, gin byproduct	--	0.40	Based on data provided in MRID 48156901.
Pecan	0.5	1.0	Harmonizes with Codex MRL.
Sugarcane, cane	0.02	0.10	Harmonizes with Codex MRL.
Potato Citrus Coffee Pecan Sugarcane			Add a footnote to the table stating: "* No U.S. registrations as of [*insert date*]."

See section 2.2 Tolerance Considerations, in the *Aldicarb: Draft Human Health Risk Assessment in Support of Registration Review* (dated 3/25/16) and *Aldicarb: Review of Residue Chemistry Data Submitted in Response to a Generic Data Call-In (GDCI)* (dated February 18, 2016) for additional details on the aldicarb tolerances. EPA plans to propose changes to the tolerances following the completion of the registration review interim decision.

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D. Interim Registration Review Decision

In accordance with 40 CFR Sections 155.56 and 155.58, the Agency is issuing this Interim Registration Review Decision. Except for the EDSP, ESA and pollinator components of this case, the Agency has made the following Interim Registration Review Decision: (1) additional data are required at this time as discussed below; and (2) changes to the affected registrations and their labeling are needed at this time.

In this interim registration review decision, EPA is making no human health or environmental safety findings associated with the EDSP screening of aldicarb, nor is it making a complete endangered species finding or a complete assessment of effects to pollinators. Although the Agency is not making a complete endangered species finding at this time, the mitigation described in this document is expected to reduce the extent of environmental exposure and may reduce risk to listed species whose range and/or critical habitat co-occur with the use of aldicarb. The Agency's final registration review decision for aldicarb will be dependent upon the result of the Agency's ESA assessment and any necessary consultation with the Services, an EDSP FFDCA section 408(p) determination, and an assessment of non-target exposure to pollinators (bees).

E. Anticipated Data Requirements

Human Health

In the proposed interim decision, EPA indicated that it intended to issue a DCI to obtain chemical-specific dermal absorption data. Dermal toxicity studies have been submitted to the Agency in the past, but none have been acceptable. Given the previous unsuccessful attempts to fulfill this data gap, the Agency analyzed additional information provided by the registrant to refine the occupational exposure assessment. Based on this additional analysis, the Agency has determined that the occupational risks identified for aldicarb applications to sugar beets are unlikely given the conservative assumptions used in the assessment. The Agency has concluded that dermal absorption data are not required at this time to make a registration review decision. However, the Agency may require this data for future risk assessments.

Ecological - Pollinator

Consistent with EPA's June 2014 *Guidance for Assessing Pesticide Risks to Bees*[8], EPA has begun to require pollinator data where applicable. EPA intends to issue a DCI to obtain these data. EPA will provide further information and guidance on this effort in a separate action. The pollinator studies that could be required are included in Table 19 below. The Agency will require data it believes are needed to help inform the pollinator risk assessment.

[8] http://www2.epa.gov/sites/production/files/2014-06/documents/pollinator_risk_assessment_guidance_06_19_14.pdf

Table 19. Potential pollinator data requirements for aldicarb.	
Guideline Number	**Study**
850.3040**	Field testing for pollinators
Non-Guideline* (OECD 213)	Honey bee adult acute oral toxicity
Non-Guideline* (OECD 237)	Honey bee larvae acute oral toxicity
Non-Guideline*	Honey bee adult chronic oral toxicity
Non-Guideline*	Honey bee larvae chronic oral toxicity
Non-Guideline**	Residues in pollen and nectar/field residue analysis
Non-Guideline** (OECD 75)	Semi-field testing for pollinators (tunnel or colony feeding studies)

*Tier 1 (Laboratory-based studies)

**Tier 2 and 3 (Semi-field and full field colony-level studies) The need for a higher tier test for pollinators will be determined based upon lower-tiered tests and/or other lines of data and the need for a refined pollinator risk assessment.

V. NEXT STEPS AND TIMELINE

A. Interim Registration Review Decision

A Federal Register Notice will announce the availability of this interim registration review decision of aldicarb. A final decision on the aldicarb registration review case will occur after: (1) an EDSP FFDCA Section 408(p) determination, (2) an endangered species determination under the ESA and any needed Section 7 consultation with the Services, and (3) an assessment of exposure to pollinators.

B. Implementation of Mitigation Measures

Once the Interim Registration Review Decision is issued, the aldicarb registrant must submit amended labels that include the label changes in Appendix C. The revised labels must be submitted to the Agency for review within 60 days following issuance of this Interim Registration Review Decision.

VI. REFERENCES

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Appendix A: Summary of Comments on the PID and Agency Responses

Public Comments on Proposed Interim Decision

During the public comment period on the aldicarb proposed interim decision, which opened in May 2017 and closed in July 2017, the Agency received four comments. The comments were submitted by the Center for Biological Diversity (CBD), the USDA Office of Pest Management Policy (OPMP), AgLogic Chemical LLC, and the National Cotton Council (NCC). The comments in their entirety can be found in the docket, and are summarized below, along with the Agency responses. The comments from AgLogic, the registrant, changed elements of the Agency's interim decision for aldicarb.

CBD Comment (EPA-HQ-OPP-2012-0161-0096):

CBD's comments focus on the EPA's duty to consult with the Services on the registration review of aldicarb in accordance with the ESA. The CBD comments mention various aspects of the risk assessment process, specifically use of the best available data, including all necessary data and studies, particularly to develop threatened and endangered (listed) species risk assessments, and evaluation of effects on listed species and their designated critical habitat. CBD also expressed concern regarding the rigor of the Agency's preliminary determinations regarding the effects of aldicarb on listed species and their designated critical habitat for the aldicarb registration review. In addition, CBD expressed concern about effects on pollinators and other beneficial insects, effects on human health or environmental safety concerning endocrine disruption, and any additive, cumulative or synergistic effects of the use of the pesticide.

EPA Response:

EPA has reviewed CBD's comments and plans to address many of the concerns regarding listed species as part of the implementation plan for assessing the risks of pesticides to listed species based on the recommendations of the April 2013 National Academy of Sciences (NAS) report. See *Endangered Species Assessment* in section 3 of this document for more information. EPA will address concerns specific to aldicarb, particularly with regard to pollinators, ESA, and endocrine disruption, in connection with the development of its final registration review decision for this pesticide. See *Endocrine Disruptor Screening Program* in section 3 of this document for more information regarding endocrine disruption. EPA is currently developing an Agency policy on how to consider claims of synergy being made by registrants in their patents. EPA intends to release this policy for public comment. After the Agency has received and considered public comment on the proposed policy, and once that policy has been finalized, EPA will consider its implications on EPA's final decision for aldicarb.

USDA Comment (EPA-HQ-OPP-2012-0161-0097):

The USDA OPMP is supportive of the Agency's decision to register aldicarb and noted aldicarb's benefits to U.S. agriculture. USDA commented that the mitigation measures – removing the foliar peanut application, requiring specific depths for soil-applied granules, and removing the T-band application method – will not be disruptive to pest management strategies.

EPA Response:

The Agency thanks USDA for their comment on the proposed interim decision.

NCC Comment (EPA-HQ-OPP-2012-0161-0099):

The NCC noted the historical safe labeled use of aldicarb and the benefit of aldicarb to the cotton industry, particularly for control of nematodes. NCC commented that they regret that the T-band application is discontinued, but appreciate the Agency's registration review and proposed registration of aldicarb with new mitigation measures.

EPA Response:

The Agency thanks NCC for their comment on the proposed interim decision.

AgLogic Chemical LLC (EPA-HQ-OPP-2012-0161-0098)

Comment 1: *AgLogic requested that the Interim Decision be revised to eliminate the SWCC drinking water exposure estimates from the DRA to assure the public that their commodities treated with aldicarb are safe to eat as well as for the public who want to have confidence that the Agency is assuring the safety of the food supply.*

Response 1: The Agency has retained the information from the DRA in the interim decision to provide a transparent and clear history of how the Agency has come to its decision.

Comment 2: *AgLogic commented that aldicarb is not registered for use in Mexico and as a result, potato imports from Mexico would not contribute to the dietary component of aldicarb in domestic consumption.*

Response 2: Mexico indicated that aldicarb is registered as a granular application. Therefore, imported foods from Mexico are included in the dietary exposure assessment.

Comment 3: *AgLogic requested that the Agency review information that they provided regarding applications of aldicarb to sugar beets prior to making a decision for a data call-in for dermal absorption data.*

Response 3: Given that there have been previous unsuccessful dermal toxicity studies submitted to fulfill this data gap, the Agency analyzed additional information provided by AgLogic to refine the occupational exposure assessment. Based on this additional analysis, the Agency has determined that the occupational risks identified for aldicarb applications to sugar beets are unlikely given the conservative assumptions used in the assessment. The Agency has concluded that although dermal absorption data are still a data gap, the Agency is not requiring it at this time to make a registration review decision. However, the Agency may require this data for future risk assessments.

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Appendix B: Summary of Actions for Aldicarb					
Registration Review Case#: 0140 PC Code: 098301 Chemical Type: Insecticide Chemical Family: Carbamate Mode of Action: AChE inhibition					
Affected Population(s)	Source of Exposure	Route of Exposure	Duration of Exposure	Potential Risk(s) of Concern	Required Action(s)
• Residential	• Drinking water	• Oral	• Acute	• Direct	• Clarification of soil depth required for placement of aldicarb granules. • Delete foliar applications for peanut use. • Delete T-band application method for all crops. • Increase minimum drinking water well setback from 50- to 300-feet in AL, GA, SC.
• Mammals • Birds • Aquatic Animals	• Dietary • Drinking water	• Ingestion	• Acute • Chronic	• Direct	• Clarification of soil depth required for placement of aldicarb granules. • Delete foliar applications for peanut use. • Delete T-band application method for all crops.

Appendix C: Aldicarb Label Table

(For products containing the active ingredient aldicarb)

Summary of Required Labeling Changes for Aldicarb Uses		
Description	Amended Labeling Language for Aldicarb Use Products	Placement on Label
End Use Products		
Restricted Use Box Toxicity Statement	**"DUE TO ACUTE ORAL, DERMAL, and INHALATION TOXICITY and TO GROUND WATER CONTAMINATION"**	Restricted Use Box
Mode of Action	"Aldicarb is an N-methyl carbamate that inhibits cholinesterase."	Statement under the First Aid table
Precautionary Statements	"Fatal if swallowed, absorbed through the skin or inhaled. Do not get in eyes, on skin, or on clothing. Do not breathe dust. Rapidly absorbed through skin or eyes. Causes cholinesterase inhibition. Wash thoroughly with soap and water after handling, before eating, drinking, chewing gum, using tobacco or using the toilet. Wear coveralls worn over long-sleeved shirt and long pants, socks, chemical resistant footwear, and gloves. Keep away from domestic animals."	Precautionary Statements under the heading "Hazards to Humans and Domestic Animals Danger", first paragraph
Personal Protective Equipment (PPE)	**"PERSONAL PROTECTIVE EQUIPMENT (PPE):** All handlers (including mixers, loaders and applicators) must wear a minimum of coveralls over a long-sleeved shirt and long pants, chemical-resistant gloves made of any waterproof material, and chemical-resistant footwear plus socks. In addition, during mixing and loading, equipment cleaning or repair, spill clean up, or other handling activities, handlers must wear protective eyewear (goggles or face shield), a chemical-resistant apron, and use a filtering face piece, half face or full face NIOSH approved respirator (TC-84A) with any N, R, or P filter; OR a NIOSH approved powered air purifying respirator (TC-21C) with an HE filter."	Precautionary Statements under the heading "Hazards to Humans and Domestic Animals Danger"
Engineering Controls for Enclosed Cab Vehicles	Applicators using an enclosed cab that meets the definition in the Worker Protection Standard for Agricultural Pesticides [40 CFR 170.240(d)(5)] may wear reduced personal protective equipment provided they wear a long-sleeved shirt, long pants, and shoes plus socks and, are provided, have immediately available, and use in an emergency, such as a broken package, spill, or equipment breakdown: chemical-resistant gloves made of any waterproof material, a chemical-resistant apron, chemical resistant footwear,	Precautionary Statements under the heading "Hazards to

	protective eyewear (goggles or face shield), and a filtering face piece, half face or full face NIOSH approved respirator (TC-84A) with any N, R, or P filter; OR a NIOSH approved powered air purifying respirator (TC-21C) with an HE filter. Applicators must take off any PPE that was worn in the treated area before reentering the cab, and store all such PPE in a chemical-resistant container, such as a plastic bag, to prevent contamination of the inside of the cab."	Humans and Domestic Animals Danger"
User Safety Requirements	"Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.	User Safety Requirements
Physical and Chemical Hazards	"**PHYSICAL AND CHEMICAL HAZARDS** Do not allow contact with oxidizing agents. Hazardous chemical reaction may occur."	Physical and Chemical Hazards section before the heading "Directions for Use"
RESTRICTIONS	"Immediately deep disk any spills at row ends to a depth of at least 2 to 4 inches to prevent birds from feeding on exposed granules."	RESTRICTIONS before "Ground Water Restrictions" section
Directions for Use	"To provide maximum performance and to minimize hazard to birds, granules must be placed into bottom of furrow and immediately covered with soil by mechanical means. If granules are placed in the seed furrow at planting, seed and granules must be covered with 1-inch or more of soil. To ensure satisfactory germination and emergence make sure that seeds are planted at the proper depth for the planting conditions (soil type, soil moisture, soil temperature). For side-dress applications, granules should be placed in the bottom of the furrow and covered with 2 to 6 inches of soil. For all applications, cover or immediately soil incorporate granules spilled during loading, at row ends, or elsewhere to ensure the granules are completely covered with at least 2 to 4 inches of soil. When a range of rates are specified, use the higher rate if pest infestations are expected to be severe."	Directions for Use
Cotton application instructions At planting	"Apply granules in the seed furrow and immediately cover seed and granules with 1-inch or more soil. If seeds and granules are hill-dropped, rates may be reduced by one-half."	Cotton Application Instructions under the heading "Directions for Use"

Cotton application instructions Side Dress Application or Split Application	"Side-dress granules in a furrow that is 6 to 10 inches to one or both sides of plant row and 2 to 3 inches deep. Immediately cover granules with soil by closing furrow. Adjust applications to minimize root pruning. Apply before populations reach an economic threshold. Apply for control of moderate populations. Only suppression may be expected for heavy populations of sweet potato whitefly, especially the poinsettia (B) strain (silver leaf)."	Cotton Application Instructions under the heading "Directions for Use"
Restrictions for Cotton	"**RESTRICTIONS FOR COTTON** • The maximum single at-plant application rate is 7 pounds product (1.05 lbs a.i.) per acre. See application restrictions on vulnerable soils. • The maximum single side-dress application rate is 14 pounds product (2.1 lbs a.i.) per acre in California and 5 pounds product (0.75 lbs. a.i.) per acre in other states. See application restrictions on vulnerable soils. • Do not exceed a total of 21 pounds product (3.15 lbs a.i.) per acre per year in California or 12 pounds product (1.8 lbs a.i.) per acre per year in other states for all applications to cotton. See application restrictions on vulnerable soils where a combination of an At-Planting and Side Dress application is planned. • Apply only between March 1 and September 1 when used in California. • Do not make more than one at-planting application and one post-emergence application per crop. • Make side-dress applications close enough to plants to allow good uptake by the roots without injury to the plants from root pruning. • Do not apply within 90 days of harvest. • Do not feed cotton forage to livestock or allow livestock to graze in treated area. • Immediately deep-disk any spills at row ends or elsewhere to ensure the granules are covered with at least 2 to 4 inches of soil."	RESTRICTIONS FOR COTTON under the heading "Directions for Use"
Dry Beans application instructions At planting for all pests controlled except nematodes	"Apply granules in the seed furrow and immediately cover seed and granules with 1-inch or more of soil. Granules may be placed in the seed furrow if the rate does not exceed 5.5 ounces per 1,000 feet of row (5 pounds per acre on 36-inch rows). **OR** Apply granules in a furrow that is 2 to 3 inches to the side of the seed row and 2 to 3 inches deep. Immediately cover granules with soil by closing furrow."	Dry Beans Application Instructions under the heading "Directions for Use"
Dry Beans application instructions At planting for nematodes	"Apply granules in a 4-inch band and immediately cover with 1 to 3 inches of soil. Plant into treated zone. **OR** Where furrow irrigation is used, side dress granules 3 to 4 inches deep and 3 inches from seed row on the water furrow side. Immediately cover granules with soil by closing side dress furrow."	Dry Beans Application Instructions under the heading

		"Directions for Use"
Restrictions for Dry Beans	"**RESTRICTIONS FOR DRY BEANS** • For use only in Colorado, Oregon, Washington, Idaho, and Michigan. • Do not exceed a total of 14 pounds product (2.1 lbs a.i.) per acre per season. • Treatments in excess of 5.5 ounces per 1,000 feet of row (5 pounds product (0.75 lbs a.i.) per acre on 36 inch rows) made directly to the seed furrow may delay plant emergence and reduce plant stand. • Do not make more than one application per crop. • Do not harvest within 90 days of treatment. • Do not feed green forage, hay or straw to livestock. • Do not allow livestock to graze in treated areas before harvest. • Do not use green pods as food for humans. • Immediately deep-disk any spills at row ends or elsewhere to ensure the granules are covered with at least 2 to 4 inches of soil."	RESTRICTIONS FOR DRY BEANS under the heading "Directions for Use"
Peanuts application instructions At planting	"Apply granules in the seed furrow and immediately cover seed and granules with 1-inch or more of soil."	Peanuts Application Instructions under the heading "Directions for Use"
Peanuts crop & time of application Split Application	**Split Application** (Alabama, Florida, Georgia, North Carolina, Oklahoma, Texas and Virginia Only) **At time of planting and/or Post-emergence application** Apply prior to peg initiation but no later than 40 days after emergence and prior to last cultivation. In the States of AL, FL, GA and SC, if an **At Planting and/or a Post-emergence Application** is planned and if a vulnerable soil is present and the water table is less than 25 feet below ground surface, do not apply within **1,100 feet** of a drinking water well unless it is known or reasonably believed based upon authoritative sources that such wells are either cased to 100 feet below the ground level or a minimum of 30 feet below the water table. If it is not known whether the water table is greater than 25 feet below ground surface, assume that the water table is less than 25 feet below ground surface.	Peanuts Crop & Time of Application under the heading "Directions for Use"

Peanuts application instructions Split Application	"**At-Planting**: Apply granules in the seed furrow and immediately cover seed and granules with 1-inch or more of soil. **Post-emergence**: Side-dress granules in a furrow that is 8 to 12 inches to both sides of plant row and 1 to 3 inches deep. Immediately cover granules with soil by closing furrow. Adjust applications to minimize root pruning."	Peanuts Application Instructions under the heading "Directions for Use"
Restrictions for Peanuts	"**RESTRICTIONS FOR PEANUTS** • Do not make more than one application per crop per year in states other than Alabama, Florida, Georgia, North Carolina, Oklahoma, Texas and Virginia. • The maximum single At-Plant application rate is 7 pounds product (1.05 lbs a.i.) per acre. See application restrictions on vulnerable soils. • The maximum single post-emergence application rate is 10 pounds product (1.5 lbs a.i.) per acre. See application restrictions on vulnerable soils. • Do not exceed a total of 17 pounds product (2.55 lbs a.i.) per acre per year for all applications to peanuts. See application restrictions to vulnerable soils where a combination of an At-Planting and post-emergence application is planned. • Do not make the split application to Spanish peanuts or other short season varieties (a minimum of 90 days is required between post-emergence applications and harvest). • Do not make post-emergence foliar applications. • Do not harvest within 90 days of application. • Do not hog-off treated fields. • Do not allow livestock to graze in treated areas before harvest. • Do not feed hay or vines to livestock. • Immediately deep-disk any spills at row ends or elsewhere to ensure the granules are covered with at least 2 to 4 inches of soil."	RESTRICTIONS FOR PEANUTS under the heading "Directions for Use"
Soybeans application instructions At planting for all pests controlled except nematodes	"Apply granules in the seed furrow and immediately cover seed and granules with 1-inch or more of soil. Granules may be placed in the seed furrow if the rate does not exceed 5.5 ounces per 1,000 feet of row (6 pounds per acre on 30-inch rows). **OR** If rate exceeds 5.5 ounces per 1,000 feet of row (6 pounds per acre on 30-inch rows), apply granules in a 4-inch band over open seed furrow and immediately cover seed and granules with 1- inch or more of soil."	Soybeans Application Instructions under the heading "Directions for Use"
Soybeans application instructions At planting for nematodes	"Apply granules in a 4-inch band over open seed furrow and immediately cover seed and granules with 1-inch or more of soil."	Soybeans Application Instructions under the heading

		"Directions for Use"
Restrictions for Soybeans	**"RESTRICTIONS FOR SOYBEANS** • For use only in Georgia, North Carolina, South Carolina, and Virginia. • Do not make more than one application per crop. • Do not harvest within 90 days of treatment. • Do not allow livestock to graze in treated areas before harvest. • Do not feed green forage, hay, or straw to livestock. • Treatments in excess of 5.5 oz per 1,000 feet of row (6 pounds product (0.9 lbs a.i.) per acre on 30 inch rows) made directly to the seed furrow may delay plant emergence and reduce plant stand. • Immediately deep-disk any spills at row ends or elsewhere to ensure the granules are covered with at least 2 to 4 inches of soil."	RESTRICTIONS FOR SOYBEANS under the heading "Directions for Use"
Sugar Beets application instructions At planting or within one week before planting for nematodes	"Apply granules in a 4-inch band and immediately cover with 1 to 4 inches of soil. Plant seed into treated zone. OR Where furrow irrigation is employed for seed germination, drill granules 3 to 4 inches deep and 3 inches from seed row on water furrow side."	Sugar Beets Application Instructions under the heading "Directions for Use"
Sugar Beets application instructions At planting for aphids, leafminers, leafhoppers	"Drill granules 1 to 3 inches below seedline. Granules can be placed in seed furrow if rate does not exceed 7 pounds per acre. Repeat applications will be required for continued protection against virus vectors (aphids and leafhoppers)."	Sugar Beets Application Instructions under the heading "Directions for Use"
Sugar Beets application instructions At planting for sugar beet maggot	"Apply granules in a 2 to 3-inch band over open seed row and immediately cover seed and granules with 1-inch or more of soil. OR Where furrow irrigation is employed for seed germination, drill granules 2 inches deep and 2 inches from seed row on water furrow side."	Sugar Beets Application Instructions under the heading "Directions for Use"

Sugar Beets application instructions At planting plus Post-emergence (split applications) for nematodes	"**At Planting**: Apply granules in a 4 to 6-inch band and immediately cover with 1 to 4 inches of soil. Plant seed into treated zone. OR Where furrow irrigation is employed for seed germination, drill granules 3 to 4 inches deep and 3 inches from seed row on water furrow side. **Post-emergence**: Side-dress granules in a furrow that is 4 to 8 inches to both sides of plant row and 1 to 3 inches deep. Immediately cover granules with soil by closing furrow. OR Where furrow irrigation is employed side-dress granules 4 to 8 inches to water furrow side of plant row and 1 to 3 inches deep (about depth of water furrow). Immediately cover granules with soil by closing side-dress furrow. Irrigate soon after application. Apply within 60 days after planting."	Sugar Beets Application Instructions under the heading "Directions for Use"
Sugar Beets application instructions Post-emergence for sugar beet root maggot	"Side-dress granules in a furrow to both sides of plant row and 1 to 3 inches deep. Immediately cover granules with soil by closing side-dress furrow. OR Where furrow irrigation is employed side-dress granules 4 to 8 inches to water furrow side of plant row and 1 to 3 inches deep (about depth of water furrow). Immediately cover granules with soil by closing side-dress furrow. Irrigate soon after application. Apply within 60 days after planting."	Sugar Beets Application Instructions under the heading "Directions for Use"
Sugar Beets application instructions Post-emergence for aphids, leafminers, leafhoppers	"Apply as above. A repeat application may be required for continued protection against virus vectors (aphids, leafhoppers). Apply within 60 days of planting."	Sugar Beets Application Instructions under the heading "Directions for Use"
Sugar Beets application instructions Post-emergence for nematodes	"Apply as above. Apply within 60 days after planting. In California, apply within 30 days after planting."	Sugar Beets Application Instructions under the heading "Directions for Use"
Restrictions for Sugar Beets	"**RESTRICTIONS FOR SUGAR BEETS** • For use only in California, Colorado, Idaho, Montana, Nebraska, Oregon, Washington and Wyoming. • Apply only between March 1 and September 1 when used in California. • Do not exceed a total of 28 pounds product (4.2 lbs a.i.) per acre per year in California and 33 pounds product (4.95 lbs a.i.) per acre per year in other states for all applications to sugar beets.	RESTRICTIONS FOR SUGAR BEETS under the heading

	• Do not make more than one at planting application and two post-emergence applications per crop. • Do not apply within 90 days of harvest. • If tops are to be fed to livestock, do not apply within 120 days of harvest. • Do not use tops as food for humans. • Treatments in excess of 4.5 ounces per 1,000 feet of row (7 pounds product (1.05 lbs a.i.) per acre on 22 inch rows) made directly in the seed furrow may delay plant emergence and reduce plant stand. • Immediately deep-disk any spills at row ends or elsewhere to ensure the granules are covered with at least 2 to 4 inches of soil.	"Directions for Use"
Sweet Potatoes application instructions	"Apply granules in a 12-inch band over open furrow or soil surface and immediately cover granules with 8 to 10 inches of soil during bed forming. Place transplant in center of treated zone."	Sweet Potatoes Application Instructions under the heading "Directions for Use"
Restrictions for Sweet Potatoes	**"RESTRICTIONS FOR SWEET POTATOES** • For use only in Louisiana and Mississippi. • Maximum single application rate is 20 pounds product (3 lbs a.i.) per acre per year. • Do not make more than one application per crop. • Do not harvest within 120 days of application. • Do not feed sweet potato vines to livestock. • Immediately deep-disk any spills at row ends or elsewhere to ensure the granules are covered with at least 2 to 4 inches of soil."	RESTRICTIONS FOR SWEET POTATOES under the heading "Directions for Use"
Limit of Warranty and Liability for Product Registration 87895-1	Specify "AgLogic Chemical, LLC" for references to "this company."	Limit of Warranty and Liability
Restricted Use Box Toxicity Statement	**"DUE TO ACUTE ORAL, DERMAL, and INHALATION TOXICITY and TO GROUND WATER CONTAMINATION"**	Restricted Use Box above the "Environmental Precautions and Soil Type Restriction Tables" heading

Environmental Precautions	**"USE RESTRICTIONS** ALDICARB HAS THE POTENTIAL TO MOVE INTO SHALLOW GROUND WATER."	Environmental Precautions section of the "Environmental Precautions and Soil Type Restriction Tables", first sentence
Soil Type Restriction Table	Remove soil type restriction tables for Delaware and Minnesota.	Soil Type Restriction Table in the "Environmental Precautions and Soil Type Restriction Tables"
Soil Type Restriction Table	Remove references to "(Pegging)" in the soil type restriction tables.	Soil Type Restriction Table in the "Environmental Precautions and Soil Type Restriction Tables"
Soil Type Restriction Table	State - "AL, GA, and SC" Soils for which restrictions apply - "Other Soils, All Crops" Additional restrictions – "[*Insert product name*] may not be applied within 300 feet of any drinking water well."	Soil Type Restriction Table in the "State Specific Ground Water Limitations" in "Directions for Use" section

Soil Type Restriction Table	For the state of Alabama, replace the first sentence (If a vulnerable soil is present and the water table is less than 25 feet below ground surface, do not apply within **300 feet** of a drinking water well unless it is known or reasonably believed based upon authoritative sources that such wells are either cased to 100 feet below ground level or a minimum of 30 feet below the water table.) with "[*Insert product name*] may not be applied within 300 feet of any drinking water well."	Soil Type Restriction Table in the "State Specific Ground Water Limitations" in "Directions for Use" section
Soil Type Restriction Table	For the state of Georgia, replace the first sentence (If a vulnerable soil is present and the water table is less than 25 feet below ground surface, do not apply within **300 feet** of a drinking water well unless it is known or reasonably believed based upon authoritative sources that such wells are either cased to 100 feet below ground level or a minimum of 30 feet below the water table.) with "[*Insert product name*] may not be applied within 300 feet of any drinking water well."	Soil Type Restriction Table in the "State Specific Ground Water Limitations" in "Directions for Use" section
Soil Type Restriction Table	For the state of South Carolina, replace the first sentence (If a vulnerable soil is present and the water table is less than 25 feet below ground surface, do not apply within **300 feet** of a drinking water well unless it is known or reasonably believed based upon authoritative sources that such wells are either cased to 100 feet below ground level or a minimum of 30 feet below the water table.) with "[*Insert product name*] may not be applied within 300 feet of any drinking water well."	Soil Type Restriction Table in the "State Specific Ground Water Limitations" in "Directions for Use" section
Resistance Management for products labeled for Agricultural Uses	List resistance management language from PRN 2017-1. (https://www.epa.gov/pesticide-registration/pesticide-registration-notices-year)	Directions for Use